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Medical Records

Place your test results and other documents here.

Welcome to the Crohn's & Colitis Clinic

Departments of Internal Medicine and Pediatrics
Division of Gastroenterology

Managing Editor: Kristen Boardman, PA-C

Contributors: Leslie Aldrich, MD, Grace Elta, MD, John Del Valle, MD, Shail Govani, MD, Peter Higgins, MD, Terry Logan, RN, Beth Manoogian, MD, Swati Patel, MD, Michael Rice, MD, Ryan Stidham, MD, Lisa Sylvest, RN, Akbar Waljee, MD

We are glad you have chosen us to help you manage your inflammatory bowel disease. This binder is a resource that will help you take an active role in your medical care. It will also help you understand inflammatory bowel disease and how it will impact your life. We have included our contact information, as well as pages to record your test results and current medicines. You will also find information about treatment options and other helpful resources.

The quality of your care is our number one goal. We are a team of physicians, physician assistants, registered nurses, and medical assistants. We want to partner with you to make sure you have the best quality of life possible. To do this, we ask you to come to all of your visits and take your medicines as prescribed by your gastroenterologist.

We need to see you at least once every 6 to 12 months and maybe more often, if necessary. Your well-being is our number one concern. If it is easier, you may have some blood tests done at a lab close to your home. Please ask the lab to fax us the results. If you are not able to attend your scheduled clinic visits or have lab tests done as needed, we are not able to care for you safely and your health can be affected. We look forward to getting to know you. We will work together toward your goals so that you can live your life to the fullest.

Important Things to Know Up Front

- ✓ If you are ill or are having side effects between 8:00 AM and 4:30 PM on a weekday call your nurse (see phone number on page 12). **If you are thinking of going to the ER, call your nurse first because we will try to see you right away.** If you cannot reach us and you are seriously ill, please do not wait until the next day; go to the ER right away.
- ✓ When you call the Crohn's & Colitis Clinic be prepared to tell us exactly what symptoms you are having or give specific details about your concerns. Please have your **registration number** and a **list of your current medicines**. When you call, you will speak with the medical assistant who will give the message to your nurse. We will make every effort to get back to you as soon as we can. Make sure we have your correct phone number so we can reach you. We do not e-mail patients.
- ✓ If you call before 12 NOON with an urgent issue, we will make every effort to return your call by the end of the day. If for some reason you cannot reach us, and you are seriously ill, please do not wait until the next day – go to the ER right away.
- ✓ Routine calls will generally be returned within 2 to 3 days.
- ✓ It is often more effective to send us an electronic message through the Patient Portal. Please include a description of your current symptoms, and any specific questions you need answered.
- ✓ If you have an urgent question after 4:30 PM on a weekday or on the weekend, call the hospital operator at (734) 936-6267 and ask for the gastroenterologist on call. If you are calling about a child, the phone number is (734) 763-9650.
- ✓ Keep in mind that **if you are admitted to the hospital due to a flare of IBD, your outpatient IBD gastroenterologist will not see you day to day in the hospital.** One of the IBD specialists on our team will see you and oversee your care while you are in the hospital. This doctor will be in touch with your outpatient doctor about your care, as needed.
- ✓ **Do not wait until your routine appointment if you are sick.** Call your nurse, who will work closely with your doctor and the physician assistant to get an urgent visit scheduled. (UofM patients, not VA).

Important Things to Know Up Front (*continued*)

- ✓ Always tell us about any new health problems you have or any ER visits or hospital stays. Please try to bring records about your hospital stays to your visits with us. The most important records to bring are the discharge summary and reports of any tests, such as endoscopy, CT, MRI, and blood tests.
- ✓ For medicine refills, call the toll free number listed for your nurse (see page 12) and press 5 for the refill line. **Please call at least 2 working days before you will run out of your medicine (2 weeks for the VA).** If you use a mail order service, please call at least 3 weeks before you need the refill so there is enough time for your medicine to be mailed. This can often be done more quickly through the electronic messages of the patient portal.
- ✓ If you have a change in address, phone number, or health insurance, please give the new information to Hospital Registration at toll free **1-866-452-9896** Monday to Friday 6:30 AM to 8 PM or Saturday 8 AM to 1 PM. If you are taking an immunosuppressive medicine we need to be able to get a hold of you quickly. For example, the results of your lab tests may indicate that the dose of your medicine needs to be changed. For this reason, please call your nurse **as soon as you can** to give us your new phone number.
- ✓ We encourage you and your family to become members of the Crohn's & Colitis Foundation of America (CCFA) www.ccfa.org. The CCFA is a very helpful resource for anyone living with inflammatory bowel disease. Your nurse or doctor can tell you more about this group.

Meet Your Crohn's & Colitis Team

Our **doctors** possess exceptional clinical skills and have a genuine interest in your treatment.



Dr. Shrinivas Bishu
Gastroenterology



Dr. John Del Valle
Gastroenterology



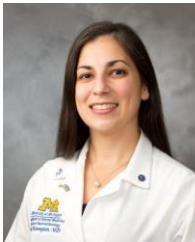
Dr. Peter Higgins
Gastroenterology



Dr. Ryan Stidham
Gastroenterology



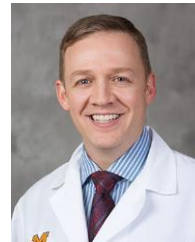
Dr. Jami Kinnucan
Gastroenterology



Dr. Beth Manoogian
Gastroenterology



Dr. Muza-Moons
Gastroenterology



Dr. Michael Rice
Gastroenterology



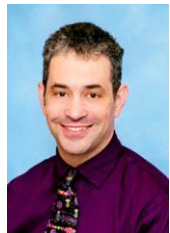
Dr. Shirley Cohen-Mekelberg
Gastroenterology



Dr. Akbar Waljee
VA Gastroenterology



Dr. Kelly Cushing
Gastroenterology



Dr. Jeremy Adler
Pediatric
Gastroenterology



Dr. Haley Neef
Pediatric
Gastroenterology



Dr. George Zacur
Pediatric
Gastroenterology

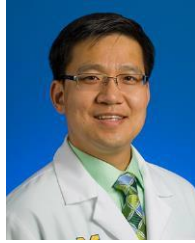
Additional Inpatient Doctors



Dr. Michelle Anderson
Gastroenterology



Dr. Matt DiMagno
Gastroenterology



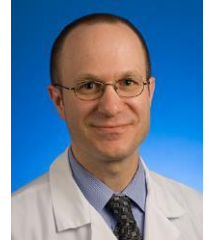
Dr. John Kao
Gastroenterology



Dr. Raani Punglia
Gastroenterology



Dr. Liz Speliotes
Gastroenterology



Dr. Erik Wamsteker
Gastroenterology

Colorectal Surgery Faculty



Dr. John Byrn
Surgery



Dr. Karin Hardiman
Surgery



Dr. Samantha Hendren
Surgery



Dr. Arden Morris
Surgery



Dr. Scott Regenbogen
Surgery

We are proud to have two of the best **physician assistants** (PAs) to better serve your needs.



Kristen Boardman, PA-C



Christine Erickson, PA-C

Our **medical assistants** (MA's) will help you schedule your appointments and make sure you are ready for your first IBD visit.



Danielle Burton, MAI



Brittney Banks, MA

Our **registered nurses** (RNs) are very knowledgeable and caring. They will help you manage your disease.



Kathy Palm, RN



Donna Heisey, RN



Valerie Hockman, RN



Teresa Stevens, RN



Tracy Krupp, RN

Our **GI Behavioral Psychologists** can help you with relaxation and stress-relieving techniques to deal with the struggles of IBD.

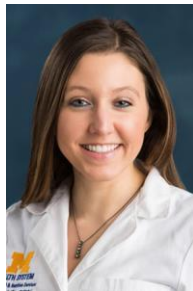


Dr. Megan Riehl



Dr. Christina Jagielski

Our **FODMAPS Dieticians** can help you learn to manage your symptoms through your daily diet.



Emily Haller, RDN



Amanda Dixon, RDN



Clinical Research Staff for Dr. Peter Higgins



Charlie Bourque, Clinical Coordinator for Dr. Ryan Stidham

Crohn's & Colitis Clinics

- **Taubman Health Center**, 1500 East Medical Center Drive, Ann Arbor, MI 48109
- **Brighton Center for Specialty Care**, 8001 Challis Road, Brighton, MI 48116
- **Northville Health Center**, 39901 Traditions Drive, Suite 210, Northville, MI 48168
- **West Ann Arbor**, 380 Parkland Plaza Ann Arbor, MI 48103

In addition to our clinic at Taubman Health Center, the following providers have a clinic at the following locations:

TC: Dr. Bishu, Dr. Higgins, Dr. Stidham, Dr. Manoogian, Dr. Del Valle, Christine Erickson, PA-C

NHC: Dr. Bishu, Dr. Kinnucan, Dr. Muza-Moons and Dr. Manoogian

BCSC: Dr. Muza-Moons and Dr. Cushing

WAA: Dr. Rice and Kristen Boardman, PA-C

| Day | Pediatric Clinic• Location | Physician | Availability |
|------------------------|-------------------------------|---|--------------|
| Monday to Friday | C.S. Mott Children's Hospital | Jeremy Adler, MD, MSc Haley Neef, MD George Zacur, MD, MS | Every day |

Crohn's & Colitis Clinic

Physician and Nurse Contact Information

How to Contact Your Doctor: To contact your doctor, call the nurse who works with your doctor. Look at the table below to determine who your nurse is and which phone number to use.

| Physician | Nurse | Local | Toll-Free |
|-----------------------------------|---|--------------|-----------------------------------|
| Shrinivas Bishu, MD | Valerie Hockman, RN | 734-936-0501 | 1-888-229-7631 |
| John Del Valle, MD | Kathy Palm, RN | 734-936-0501 | 1-888-229-7631 |
| Shirley Cohen-Mekelburg, MD | Teresa Stevens, RN | 734-936-0501 | 1-888-229-7631 |
| Kelly Cushing, MD | Tracy Krupp, RN | 734-936-0501 | 1-888-229-7631 |
| Peter Higgins, MD, PhD, MS | Valerie Hockman, RN | 734-936-0501 | 1-888-229-7631 |
| Jami Kinnucan, MD | Donna Heisey, RN | 734-936-0501 | 1-888-229-7631 |
| Beth Manoogian, MD | Teresa Stevens, MD | 734-936-0501 | 1-888-229-7631 |
| Michelle Muza-Moons, MD, PhD | Valerie Hockman, RN | 734-936-0501 | 1-888-229-7631 |
| Michael Rice, MD | Kathy Palm, RN | 734-936-0501 | 1-888-229-7631 |
| Ryan Stidham, MD | Tracy Krupp, RN | 734-936-0501 | 1-888-229-7631 |
| Akbar Waljee, MD, MSc | Susan Manor, RN Veterans Affairs Ann Arbor | 734-845-3469 | 1-800-361-8387 Extension 53469 |
| Jeremy Adler, MD, MSc (Pediatric) | Ronna Johnson, RN | 734-763-9650 | |
| Haley Neef, MD (Pediatric) | Ronna Johnson, RN | 734-763-9650 | |
| George Zacur, MD, MS (Pediatric) | Ronna Johnson, RN | 734-763-9650 | |

Crohn's & Colitis Clinic

Appointment Scheduling and Other Contact Information

| Appointment Scheduling | Local | Toll-Free |
|------------------------------------|--------------|------------------|
| Adult Crohn's & Colitis Clinic | 734-647-5944 | 1-888-229-7408 |
| Pediatric Crohn's & Colitis Clinic | 734-763-9650 | — |
| Medical Procedures Unit (MPU) | 734-936-9250 | 1-888-229-7408 |
| Radiology | 734-936-4500 | — |

| Crohn's & Colitis Program | Local | Toll-Free |
|--------------------------------------|--------------|------------------|
| Medical Assistant | | |
| Danielle Burton, MA | 734-936-0501 | 1-888-229-7631 |
| Physician Assistant | | |
| Kristen Boardman, PA-C | 734-936-0501 | 1-888-229-7631 |
| Christine Erickson, PA-C | 734-936-0501 | |

| Clinical Research Staff | Local | E-mail |
|--------------------------------|--------------|--|
| Jennifer Dixon | 734-615-4843 | higginsSCteam@umich.edu |
| Kelli Porzondek | 734-764-0507 | higginsSCteam@umich.edu |
| Tasneem Tweel | 734-647-2564 | higginsSCteam@umich.edu |
| Zachary Beringer | 734-647-4548 | higginsSCteam@umich.edu |
| Angela Theil | 734-998-1147 | higginsSCteam@umich.edu |
| Kimberly Heeringa | 734-647-1092 | higginsSCteam@umich.edu |
| Charlie Bourque | 734-615-3911 | cabjr@umich.edu |

Basic Information about Inflammatory Bowel Disease (IBD)

What is inflammatory bowel disease?

Inflammatory bowel diseases are a collection of conditions causing chronic inflammation primarily affecting the small intestine and/or colon (also known as the large intestine). The cause of IBD is not completely understood, but is believed to be related to a combination of genetic, bacterial (microbiome), and immune system factors. Current theories suggest that individuals with IBD have an immune system that has developed an aggressive response to innocuous intestinal bacteria. More than 160 genes have been linked to an increased risk or severity of IBD, however no single gene is clearly causative. While the most common area of involvement is the intestines, other regions including the skin, joints, and eyes can be affected by IBD.

There are three different types of inflammatory bowel disease.

1. **Ulcerative colitis** affects only the colon.
2. **Crohn's disease** most often affects the end of the small intestine, but it can affect any region.
3. **Indeterminate colitis** is when features of both Crohn's disease and UC are present.

What is ulcerative colitis (UC)?

Ulcerative colitis starts in the rectum and can affect the entire colon or only part of it. It may be called *proctitis* if only the rectum is affected and *left-sided colitis* if only the lower half of the colon is affected. If most of the colon is affected, it may be called *pancolitis*. The inflammation is continuous, which means that it does not stop and then start again in a different part of the colon. The inflammation is chronic, which means that it is always present, although the symptoms may come and go. Further, the inflammation is limited to the superficial layers of the colon, helping to separate UC from Crohn's disease. Inflammation can spontaneously increase, often unpredictably, leading to an increase in symptoms that are commonly called "flares." Ulcerative colitis is different from irritable bowel syndrome, infectious colitis, and ischemic colitis because it is caused by chronic immune-mediated inflammation.

What is Crohn's disease?

Crohn's disease can affect any part of the digestive tract: mouth, esophagus, stomach, proximal (duodenal and jejunal) or distal (ileum) small intestine or the colon. The most common area affected is at the end of the small intestine, the terminal ileum. The inflammation usually occurs in segments, with healthy segments in between inflamed segments. This patchy, "skip lesion" behavior of Crohn's disease is different from UC. In addition, Crohn's disease can affect deep layers of the intestine, further distinguishing it from UC. It is called Crohn's ileitis when only the ileum is affected. It is called Crohn's colitis when only the colon is affected. And it is called Crohn's ileocolitis when both the ileum and the colon are affected.

What is indeterminate colitis?

Indeterminate colitis also only affects the colon, but it is not the same as ulcerative colitis. IBD may be called indeterminate colitis when the biopsy cells under the microscope look more like cells from a person with ulcerative colitis, but with the naked eye the inflammation in the colon looks more like that of Crohn's disease. Remember, inflammation in Crohn's disease is more likely to affect isolated segments of the colon, rather than continuous stretches of the colon, as happens in ulcerative colitis. Also, in Crohn's disease the ulcerations can look deep and long.

Who is at most risk of getting IBD?

All types of IBD affect men and women equally. It can occur at any age, but often starts between the ages of 15 to 25. Crohn's disease is more common among people who have a family history of the disease, though the chance of having Crohn's if a parent or sibling has Crohn's is only approximately 5-10%. Ulcerative colitis affects about 600,000 people in the United States; Crohn's disease affects about 700,000 people in the US.

Diet clearly impacts the symptoms of IBD but does not cause IBD nor does it impact intestinal inflammation. Despite the inability to control inflammation with diet alone, dietary modifications can substantially improve symptoms of diarrhea, abdominal pain, gas, and bloating that are common in IBD.

What are the symptoms of IBD?

The symptoms of IBD partly depend on where the inflammation occurs. Inflammation in the colon often causes diarrhea, potentially bloody stools, and abdominal pain. Inflammation in the rectum also frequently causes urgency (the need to have a bowel movement quickly) and tenesmus (frequent urges to have a bowel movement, but passing very little stool). If the colitis is severe, the inflammation may extend deep into the wall of the intestine and cause abdominal pain and cramping. The severity of these symptoms varies greatly between patients.

Crohn's disease may also cause additional symptoms as a result of impacting the deeper layers of the intestine. When there is prolonged severe inflammation of the intestine in Crohn's disease, a stricture can develop. A stricture is a scar that is your body's attempt at healing inflammation; in the process this causes a narrowing of the intestine. Narrowing of a region of your intestine can make it more difficult for solids, liquid, and gas to pass. This can cause symptoms of bloating with distension of the abdomen, nausea, and sometimes vomiting especially after meals. Fistulas can also occur. Fistulas are tunnels between the intestine and another close structure like the skin, pelvis, bladder, or another section of bowel, that are the result of deep inflammation; fistulas often occur in the perianal area.

In addition to bowel symptoms, you may have other symptoms such as severe fatigue, weight loss, loss of appetite, fever, sore or red eyes, skin rashes, and pain in the large joints, such as hips, knees, or elbows. People with IBD tend to have flares with active symptoms and periods of remission with no symptoms.

What are the complications of IBD?

Bowel obstruction: In Crohn's disease if a stricture develops contents may be unable to pass through your intestine, this is called an **obstruction**. Long-term obstruction raises the pressure in the part of the intestine upstream of the blocked area. This pressure can cause the intestinal wall to burst, or **perforate**. This is quite painful and requires immediate surgery.

Abscess: In some situations, small perforations are able to be contained by the body, however these areas become infected and cause an abscess. Abscesses often lead to abdominal pain and fever and require urgent attention. When fistulas form but are unable to drain, it can also form an abscess.

Colon Cancer: Long-term inflammation of the colon can lead to precancerous changes called dysplasia; this is different from typical colon polyps which occur in everyone. When dysplasia is present the risk of developing colon cancer increases substantially. For these reasons, patients with UC or Crohn's disease affecting the colon require frequent colonoscopies to prevent the development of colon cancer, and dysplasia often requires colectomy.

Joint and Bone Problems: People with IBD also often have decreased vitamin D, which can lead to **bone loss (osteopenia or osteoporosis)**. In addition, a history of high dose steroid use can also accelerate bone loss. Therefore, we will periodically have DEXA bone density scans performed to assess bone health. Some individuals with IBD will develop an inflammatory arthritis of large or small joints; this occurs in approximately 15-20% of the IBD population.

Mineral and Vitamin Deficiency:

B12-This vitamin is important in several body functions and is absorbed at the end of the small intestine. Therefore, individuals with Crohn's disease or those with resection of the terminal ileum are at risk of B12 deficiency. B12 can be replaced by monthly injection or daily oral supplements.

Iron-Iron deficiency is common in IBD and can lead to anemia with resulting fatigue. Iron stores are often checked in the setting of anemia in IBD. Oral iron is a simple and safe means to replete iron however this can cause patient to experience an upset stomach. In some situations, especially during active inflammation, repletion with IV iron is more beneficial and better tolerated.

Kidney Stones and Gallstones: Crohn's disease in the small intestine increases the risk for kidney stones and gallstones. The risk is higher if part of the small intestine has been removed. A decreased ability to absorb fat may lead to a specific type called oxalate kidney stones. People with an ileostomy have no colon and do not develop oxalate kidney stones. A low oxalate diet may be helpful for someone who keeps getting oxalate kidney stones. To see the oxalate content of different food, go to this website: http://www.lowoxalate.info/food_lists/alph_oxstat_chart.pdf. Crohn's disease also lowers the ability to absorb bile salts, which can lead to gallstones. Poor absorption of bile salts leads to an increase in cholesterol in the bile, which may cause gallstones.

How is IBD diagnosed?

You will have a complete physical exam. You may need some tests, such as blood tests, stool tests, CT or MRI scans, and colonoscopy with biopsy. The colonoscopy will look for ulcers or inflammation in the intestine. Because most of the treatments for IBD have risks, you need to be

completely sure that you have IBD before it is treated. Your intestinal tissue will be looked at very closely under a microscope to be sure you have IBD and not an infection or another illness. There is no single perfect test to diagnose IBD. Careful interpretation of the results of testing by an experienced provider is needed to confirm the diagnosis.

How are Crohn’s disease and ulcerative colitis treated?

There is no cure for IBD at this time, although this is an important topic of current research. However, treatments are improving every year, becoming more effective and safer over time. Long term control of inflammation leads to the best outcomes in IBD.

Medicines for inflammation – Most treatments for IBD focus on reducing inflammation by reducing the overactivity of the immune system. Control of inflammation is the cornerstone of all modern treatment of IBD. Even if symptoms are controlled, optimal suppression of inflammation is the goal of treatment. Blood or stool tests to check for inflammation are part of modern disease monitoring.

Medicines for symptoms – Until the medicines start working by reducing the inflammation, you may take medicines that will help ease your symptoms such as cramping, urgency, or diarrhea. These medicines are only used when you need them.

Surgery – Surgery is a complementary means of treatment in IBD, in many cases working hand-in-hand with medical treatments. Modern care for IBD relies on a multidisciplinary approach, utilizing both medicine and surgery. Many patients respond better to medicines after damaged bowel is removed.

Stop smoking – Your treatment will work better if you don’t smoke. Besides using treatments as directed, quitting smoking is the next most important intervention that improves outcomes in Crohn’s Disease. Surprisingly, some patients with Ulcerative Colitis do better when smoking.

Diet– While diet does not improve or worsen inflammation, your diet is related to many symptoms of diarrhea, bloating, gas, and abdominal pain. Changing your diet, especially during flares, may ease your symptoms.

Complementary treatment – Herbal, alternative, or complementary therapies have not been shown to work in clinical studies, nor have they been fully tested. Although some help ease symptoms, they usually work only in very mild cases. Ask your health care team about the safety and effects of these products. Always let your health care team know if you are using them. You should not rely on complementary treatments alone to manage your IBD.

What should I know about my IBD to be an informed partner in my care?

1. Do you know if you have Crohn’s disease, ulcerative colitis, or indeterminate colitis?
2. Do you know which parts of your intestines are involved?
3. Do you know what year you first had symptoms (how long have you had IBD)?
4. Do you know if you have had any strictures, fistulas, or abscesses in the past?
5. Do you know what medicines you have taken in the past? Why did you stop taking each one?

Frequently Asked Questions about Inflammatory Bowel Disease (IBD)

1. Is there a cure?

No, IBD cannot be cured. There will be periods of remission when the disease is not active. Medicines can reduce inflammation and increase the number and length of periods of remission, but there is no cure.

2. How long will IBD last?

IBD is a lifelong (chronic) condition. A few patients find their disease becomes milder (“burned out”) after age 60, but many do not.

3. Do I have to take medicine forever?

Probably. IBD is a chronic disease, and most patients need to take medicines to ease symptoms and reduce the number and severity of flares. You may need both maintenance medicines to prevent flares and rescue medicines during the time of an active flare. Most maintenance medicines act fairly slowly.

4. Are there some medicines that can get me out of a flare quickly?

Yes. These are not used long term because of side effects. Patients will often change over from rescue medicines to long-term maintenance medicines. Rescue medicines include steroids like prednisone, and cyclosporine.

5. Why do I need to keep taking maintenance medicines when I feel well?

These medicines reduce the chances for a flare and the number of flares you will have. Some of these medicines (like infliximab, adalimumab, and certolizumab) need to be taken regularly or you can have a reaction and they will stop working for you.

6. Will surgery cure my IBD?

No, but surgery can be very helpful. For patients with ulcerative colitis, removal of 97% of the colon greatly reduces symptoms. Surgery is no picnic, but it can often markedly improve quality of life if you have severe colitis. There are several ways to reconnect the intestine after the colon is removed, each of which has benefits and drawbacks.

The effect of surgery for Crohn’s disease can often be like pushing a reset button for your IBD. The surgery can remove scarred tissue and strictures, fistulas, and abscesses that cause a lot of symptoms for which medicines are not very effective. After surgery for Crohn’s disease, maintenance medicines often work better and may prevent the need for surgery in the future.

7. Is it dangerous to suppress (weaken) the immune system for the rest of my life?

There are some risks in taking medicines to suppress your immune system. Viruses that stay in your body, like the chicken pox virus, are more likely to be activated (cause shingles) in people taking azathioprine. Bacterial infections of the skin and soft tissues are more likely in people taking anti-TNF medicines. Each medicine has its own specific risks. However, for many, the benefits of avoiding IBD flares far outweigh the risks that go with taking these medicines.

You can reduce some of these risks. Ask your doctor if vaccines would be helpful to you. Also, after several years in remission some people can take a “drug holiday” and stop the immunosuppressive medicine. This needs to be done with your doctor so that you can be closely watched with regular testing for any signs of inflammation.

8. Could anything other than IBD be causing my symptoms?

Yes, patients with IBD can get IBD-like symptoms for other reasons. Infections can cause diarrhea. Previous inflammation can cause increased sensitivity of the nerves in the intestine and make you very sensitive to abdominal cramps. Too many bacteria in the small intestine can cause bloating and gas. Because you cannot be sure, call your health care team if there is a change in your symptoms because it might be something other than a flare of IBD.

9. Are narcotics used to treat my painful symptoms?

Narcotics treat the symptoms, not the inflammation caused by IBD. Narcotics can make the inflammation worse. Research has shown that patients with IBD who use narcotics are more likely to have severe abdominal infections (abscesses), strictures, and intestinal obstruction. For this reason, narcotics are used only rarely.

10. Why not just take prednisone whenever I have a flare?

Prednisone has many side effects, including bone loss, diabetes, cataracts, emotional distress, and severe acne. In addition, the longer prednisone or other steroids are used, the less likely they are to work. That’s why prednisone is only used when, and if, you really need it to rescue you from a flare. Maintenance medicines are used to reduce your number of flares and how severe your flare symptoms are. This way, you won’t need prednisone as often. There is also evidence that taking a maintenance medicine to reduce inflammation in the colon lowers your risk for colon cancer.

Testing in IBD

Colonoscopy and Flexible Sigmoidoscopy

Why does a person with Crohn's disease or ulcerative colitis need a colonoscopy?

A colonoscopy is used to make the diagnosis of Crohn's disease or ulcerative colitis. A colonoscopy can also assess the symptoms of IBD flares and the response to treatment. A third important use of a colonoscopy is to screen for early colon cancer or to look for abnormal cells that may turn into cancer cells.

What happens before a colonoscopy?

You will get detailed instructions when your appointment is made for the colonoscopy. Starting the day before the procedure you will have to take a colon cleansing preparation or "prep". This is a special laxative that helps clear away the stool so the lining of the colon can be inspected. Many people say the "prep" is the hardest part. You must not eat any food and you can drink only clear liquids. You will need to have a driver with you because the sedatives will make you drowsy.

What happens during a colonoscopy?

A colonoscopy is usually an outpatient procedure. In the preparation area a caregiver will explain the steps of the procedure to you and also the risks involved. You will be asked to sign a consent form. You will have an intravenous (IV) line started to give you a sedative in the procedure room. In the exam room, you will lie on your left side connected to oxygen and blood pressure monitors. The sedative will make you comfortable and sleepy while the lining of the colon and the last part of the small intestine are inspected. Biopsies (tissue samples) obtained during the procedure do not cause pain.

How often do patients with ulcerative colitis or Crohn's disease need a colonoscopy?

A colonoscopy is done at the time you are diagnosed with Crohn's disease or ulcerative colitis. After that time, a colonoscopy may be done if there is a significant change in your symptoms. A routine colonoscopy is not needed unless you have had ulcerative colitis or Crohn's disease affecting the colon for more than 8 to 10 years. If you have had inflammation of the colon for that length of time, there is an increased risk for colon cancer. For that reason, and from that time on, you will need a colonoscopy every 1 to 3 years, depending on other risk factors. This is called a surveillance colonoscopy. The purpose of a surveillance colonoscopy is to screen for colon cancer or abnormal cells that may turn into colon cancer. During a surveillance colonoscopy, many random biopsies (more than 30) are obtained from the entire colon.

What happens after a colonoscopy?

You will be taken to the recovery room where your driver can join you. You will be given your colonoscopy results at this time. The biopsy results will not be ready for about a week. You may have some bloating due to the air introduced during the procedure, but this should pass quickly. You cannot drive yourself home as you may be drowsy from the sedative.

What are the possible complications of a colonoscopy?

A colonoscopy is generally very safe. Complications are rare, but may include bleeding, problems with the sedative, or a perforation (tear) in the intestinal wall. If you notice any signs of bleeding or if you have significant abdominal pain after a colonoscopy, contact your doctor as instructed on your discharge instructions.

What is a flexible sigmoidoscopy?

A flexible sigmoidoscopy is a procedure similar to a colonoscopy but the scope is smaller and only inserted a short way into the colon. The bowel preparation usually requires taking two enemas before the exam. A flexible sigmoidoscopy typically causes less discomfort than a colonoscopy. Most people without active IBD do not need a sedative beforehand. A flexible sigmoidoscopy has the same complications as a colonoscopy.

Why do some patients with ulcerative colitis need a flexible sigmoidoscopy?

Ulcerative colitis usually starts at the end of the rectum and moves upward along the colon in a continuous fashion. For this reason, some patients with ulcerative colitis are only affected in the rectum, or the rectum plus the lower part of the colon. If this is the case, a flexible sigmoidoscopy instead of a colonoscopy may be used to monitor your disease. Colon cancer surveillance, however, requires a colonoscopy, so the entire colon can be seen and biopsies can be taken. People who have had colectomy with ileoanal pouch anastomosis (an operation that removes almost the entire colon and connects the small bowel to the rectum) may have a flexible sigmoidoscopy every 1-3 years to assess rectal symptoms and to screen for colon cancer or abnormal cells that may turn into colon cancer.

Upper Endoscopy

Why do some patients with Crohn's disease or ulcerative colitis need an upper endoscopy?

Upper endoscopy (sometimes abbreviated EGD), is an exam of the upper gastrointestinal (GI) tract – esophagus, stomach, and duodenum (first part of the small intestine). Unlike a colonoscopy, which is usually required for everyone with IBD, an upper endoscopy is used only if you have upper abdominal pain, problems swallowing, or nausea. Crohn's disease may affect the upper GI tract and biopsies taken during an upper endoscopy can confirm this. The upper GI tract can on rare occasions be affected in individuals with UC. If you have Crohn's disease in the upper GI tract you may benefit from taking a medicine called a proton pump inhibitor or PPI.

What happens before an upper endoscopy?

You will get detailed instructions when your appointment is made for the upper endoscopy. You must not eat any solid food the day of the procedure and stop drinking clear liquids 2 hours before the procedure. You will need to have a driver with you because the sedatives will make you drowsy.

What happens during upper endoscopy?

An upper endoscopy is usually an outpatient procedure. In the preparation area, a caregiver will explain the steps of the procedure to you and also the risks involved. You will be asked to sign a consent form. You will have an intravenous (IV) line started to give you a sedative in the procedure room. In the exam room, you will lie on your left side connected to oxygen and blood pressure monitors. The sedative will make you comfortable and sleepy while the lining of the upper GI tract is inspected. Biopsies (tissue samples) obtained during the procedure do not cause pain. The actual procedure lasts only a short time, although you will be in the recovery area for up to several hours after the procedure.

What happens after upper endoscopy?

You will be taken to the recovery room where your driver can join you. You will be given your upper endoscopy results. The biopsy results will not be available for about a week.

How often do patients with Crohn's or ulcerative colitis need an upper endoscopy?

An upper endoscopy is done only if you have symptoms of upper GI tract problems. Many patients with IBD will never need one.

What are the possible complications of upper endoscopy?

An upper endoscopy is generally very safe. An uncommon side effect is a sore throat. Very rare complications include bleeding, problems with the sedative, or a perforation (tear) in the intestinal wall. If you notice any signs of bleeding or if you have significant abdominal pain after an upper endoscopy, contact your doctor as instructed on your discharge papers.

Capsule Endoscopy and Deep Enteroscopy

Crohn's disease often involves the small intestine. Making the diagnosis of Crohn's disease can be hard when the affected portions of the small intestine are beyond the reach of the standard scopes used in upper endoscopy or colonoscopy. The small intestine is about 20 feet long and recent advances including capsule endoscopy and deep enteroscopy have made it possible to see this area of the intestine.

What is capsule endoscopy?

Capsule endoscopy, often referred to as the "pill camera," is one way to look at the entire small intestine. The capsule, which is the size of a large pill, is swallowed. The pill travels through the intestine taking two pictures per second. A recorder worn on a belt holds the pictures. A doctor will review the pictures on a computer and send a report. You will pass the capsule in the stool. The pictures from this test may show signs of Crohn's disease. The capsule used currently is not able to take biopsies of the tissue. Because a narrowing (stricture) of the intestine may keep the capsule from moving, you may be asked to swallow a "test capsule" first.

What is deep enteroscopy?

Deep enteroscopy is a test to look at the small intestine that is beyond the reach of an endoscope or a colonoscope. Double-balloon enteroscopy, single-balloon enteroscopy, and spiral enteroscopy are all examples of deep enteroscopy. The deep enteroscopy technique uses a long

scope with an overtube to move the scope deep into the small bowel. Deep enteroscopy can be used to find signs of Crohn's disease that were seen during capsule endoscopy or on the results of other tests, like a CT scan. It can be useful in the diagnosis and care of Crohn's disease because it makes it possible to do biopsies deep within the small intestine. Also, narrowed areas of the small intestine can be dilated to open them up and improve symptoms.

Laboratory Tests

Lab tests are blood tests used to monitor how severe your disease is, your response to treatment, and the effects of your medicines.

Common blood tests

- C-reactive protein A high level may indicate a flare or poor control of inflammation with medicine.
- Hemoglobin/Hematocrit A low count may suggest bleeding and anemia. Testing the levels of iron, vitamin B12, and folic acid in the blood can help to figure out the cause of anemia.
- White blood cell count A high count is a sign of inflammation or infection. A low count may be a side effect of a medicine, which means your dose may need to be decreased or stopped.
- Platelet count A low platelet count may be a side effect of a medicine, which means your dose may need to be decreased or stopped. A low count increases your risk for bleeding. A high platelet count can be a sign of inflammation.
- Comprehensive profile This group of lab tests measures the effects of medicines on electrolytes (sodium, potassium, etc.), liver function (bilirubin, albumin, AST, ALT, alkaline phosphatase), and kidney function (BUN, creatinine).

Common stool tests

- Fecal calprotectin A high level indicates intestinal inflammation which may be due to a flare or poor control of inflammation with medicine.

Blood tests for diagnosis

The following blood tests may help to identify what type of IBD you have. These tests do not provide a firm diagnosis. The results of these tests are used along with your symptoms, colonoscopy results, and radiology exams to determine your final diagnosis. These tests are often done before surgery.

- ANCA antibodies More commonly positive in ulcerative colitis.
- ASCA,
OMP-C, and
CBIR antibodies More commonly positive in Crohn's disease.

Testing for inflammation

- **Blood tests** An increased erythrocyte sedimentation rate (ESR or “sed rate”) and an increased level of C-reactive protein (CRP) are markers of inflammation. These tests assess how severe your disease is and also measure your response to treatment.

- **Stool tests** The levels of lactoferrin and calprotectin in stool are a measure of white blood cells. High levels mean your disease may be active. Low levels mean your disease may not be active. Low levels may also be a sign that your medicines are working. These tests are usually more helpful if they are repeated regularly.

Azathioprine and mercaptopurine testing

- **TPMT enzyme** Usually done only once, before you start taking azathioprine or mercaptopurine.

- **6 TG** May be ordered once or twice a year. A high level of 6 TG may be linked to a low white blood cell count, which means your dose of medicine may need to be lowered. A low level usually means that a higher dose of medicine is needed to get a better response.

- **6-MMP** A high level of 6-MMP may be linked to liver toxicity.

- **Amylase/lipase** A high level may mean inflammation of the pancreas (pancreatitis).

- **Thiomon** A test that analyzes CBC and Comprehensive profile blood testing to see how well you are responding to the medicine.

Anti-TNF testing

- **Infliximab level and antibodies to infliximab** Measures level of infliximab (Remicade®) and is usually done right before your next infusion. A low level usually means that the dose is too low or your body is clearing it too quickly from your system. Your dose may need to be increased. The test also shows if your body has made antibodies that work against infliximab. If the results are positive, you may need to switch to a different anti-TNF medicine (e.g., Humira® or Cimzia®).

- **Adalimumab level and antibodies to adalimumab** Measures level of adalimumab (Humira®). A low level means that the dose is too low or your body is clearing it too quickly from your system. Your dose may be increased. The test also shows if your body has made antibodies that work against adalimumab. If the results are positive, you may need to switch to a different anti-TNF medicine (e.g., Remicade® or Cimzia®).

- **PPD** Skin test done before starting an anti-TNF medicine to make sure you do not have tuberculosis (TB).

- **QFTB** Blood test done before starting an anti-TNF medicine to make sure you do not have tuberculosis (TB).

- Hepatitis B virus antigen Lab test that shows if you have a hepatitis B virus infection now.
- Hepatitis B virus antibody Blood test that shows if you are immune to the hepatitis B virus.
- ANA (anti-nuclear antibody) This test can be positive in up to 20% of people who take an anti-TNF medicine. A positive test may also be a sign of arthritis or a lupus-like reaction, which may mean you need to switch to a different anti-TNF medicine.

Testing for infections: *Clostridium difficile* (C. diff) and cytomegalovirus (CMV)

Colon infections are common in people with IBD. Your stool or blood may be “cultured” to find the type of infection you have and to find out what medicine would work best to treat it.

Antibiotics or antivirals are used to treat colon infections.

- C. diff toxin Stool test that is done if you have diarrhea. Taking antibiotics or having IBD in the colon can increase the risk of getting C. diff infection.
- CMV serology/PCR Blood test that is done if you continue to have diarrhea that does not seem to be related to your disease and if the results of your C. diff toxin test are negative.

Osteoporosis Monitoring

Vitamin D is needed for calcium to be absorbed in your intestine. In IBD (especially Crohn’s disease), vitamin D is not absorbed as well, so there is an increased risk for osteoporosis and bone fractures.

- Vitamin D level Low levels mean you may need to take vitamin D pills. For more information about the diagnosis and treatment of osteoporosis see *Preventing Bone Loss* in the section *Maintaining My Health*.

Imaging Tests

Abdominal x-ray series – An abdominal x-ray is a picture of structures and organs in the belly. The cause of pain in the abdomen or the cause of ongoing nausea and vomiting may show up on the x-ray. In IBD, an x-ray is helpful to look for a dilated or perforated intestine, which can be a complication of the disease. An abdominal x-ray can show if there is air in the abdomen, which is a sign of a perforation.

Barium enema – This test provides a detailed view of the inner surface of the colon. Problems with the structure of the colon, such as narrowed areas (strictures) can be detected with this test. Barium enemas also make it easier to monitor inflammation. A barium enema, or lower GI exam, is an x-ray exam of the large intestine (colon and rectum). To make the intestine visible on an x-ray, the colon is filled with a dye containing barium. This is done by pouring the dye through a tube inserted into the anus. The barium blocks the x-rays so the colon, which is filled with

barium, will show up clearly on the x-ray. There are two types of barium enemas. In a single-contrast study, the colon is filled with barium. In a double-contrast or air-contrast study, the colon is first filled with barium and then the barium is drained out, leaving only a thin layer of barium on the wall of the colon. The colon is then filled with air.

Barium upper GI (UGI) – This test is used to find narrowing (strictures) in the upper GI tract as well as ulcers and inflamed areas of the intestine in people with Crohn’s disease. This exam looks at your esophagus, stomach, and the first part of your small intestine. You will be given a barium solution to drink. A doctor watches the movement of the barium through your esophagus, stomach, and the first part of the small intestine. Several x-ray pictures are taken at different times and from different views during the exam. A small bowel follow-through may be done right after a UGI to look at the rest of the small intestine. An exam of just the throat and esophagus is called an esophagram (or barium swallow).

Computed tomography enterography (CTE) – This test is similar to a routine CT scan except you drink transparent contrast material (dye) before the CT scan is started, rather than the chalky-tasting barium contrast. The contrast material allows for the small intestine to be seen more clearly. Contrast material may also be given through an intravenous (IV) line, which shows the small intestine even more clearly. During the test, you will lie on a table that is attached to the CT scanner, which is a large doughnut-shaped machine. The CT scanner sends x-rays through the area of the body being studied. Each rotation of the scanner takes less than a second and provides a picture of a thin slice of the abdomen. All of the pictures are saved on a computer. They also can be printed. This has become useful to study diseases, such as Crohn’s disease. While a routine CT can detect the complications of Crohn’s disease, such as fistula and abscess, CTE clearly shows the small bowel inflammation that occurs in Crohn’s disease. As a result, CTE is becoming the first-line of testing for IBD, and is also being used to monitor the disease over time. CTE is also used to diagnose other disorders of the small intestine.

Computed tomography (CT) – Routine CT with chalky oral contrast that you drink is not as helpful as CTE for IBD, but it may be used in some cases. Sometimes contrast material is given through an intravenous (IV) line so the intestines can be seen more clearly.

Dual-energy x-ray absorption (DEXA) – Many IBD patients have taken steroids, which can lower bone density. DEXA measures bone density to find out if you have *osteopenia* (abnormally low bone density) or *osteoporosis* (severely low bone density). This test can help predict your chances of having a broken bone. There are no known risks from having a DEXA. For more information about the diagnosis and treatment of osteoporosis see *Preventing Bone Loss* in the section *Maintaining My Health*.

Fistulogram – This test is done for people with Crohn’s disease to learn about a fistula and its channel (tract). It is done under anesthesia by a radiologist. Contrast dye is injected into the fistula and x-rays are taken. This test more clearly shows the site of the fistula and where the material from the intestine goes; for example, from the bowel to the anus, bladder, muscle, or skin. This may allow setons (silk string or rubber band) to be placed around the channel so that an infection (abscess) does not form as it heals.

Magnetic resonance enterography (MRE) – This is often used instead of a CTE so that you are not exposed to radiation. An MRE involves a powerful but harmless magnetic field and radio waves like the kind that transmit your favorite FM music. The radio waves combine with the magnetic field to produce very clear pictures of parts of the body such as the small intestine. Contrast material is given through an intravenous (IV) line so that your small intestine can be seen more clearly. Because the MRE scan involves the use of a powerful magnet, you will be asked questions about whether you have any implanted devices such as a cardiac pacemaker, a cerebral aneurysm clip, a neurostimulator, or a hearing aid. You will also be asked if you have any metal shrapnel in your body or any metal fragments in your eyes.

Magnetic resonance imaging (MRI) – Sometimes people with IBD have symptoms in other parts of the body, besides the GI tract. These are called extra-intestinal symptoms. A common extra-intestinal symptom is joint pain or arthritis. When this affects the very low back, where the pelvis attaches to the spine, it is called sacroiliitis. An MRI is a very sensitive way to diagnose this condition. Like an MRE, it uses a harmless magnetic field and radio waves to create pictures. A special MRI called MRCP may be done to look for problems in the bile duct system. Another kind of special MRI uses a fistula protocol to see where fistulas go.

Small bowel follow-through (SBFT) – This test is done for people with Crohn’s disease to find narrow areas (strictures), ulcers, and inflamed areas in the lower part of the small intestine. The time needed for this test may be as little as 1 hour, but it may last 4 to 5 hours as it depends on how actively your intestinal tract is working. It may take longer if you have a blockage. You will drink several 7-ounce glasses of barium, although the final number of glasses depends on how long it takes the barium to travel through your small intestine. Abdominal x-ray pictures are taken at different times, from 15 minutes to 1 hour or more, depending on the activity of your intestine.

Treatment Options in IBD

Medicines

5-ASAs



What are 5-ASAs?

Aminosalicylates are a type of medicine used to treat ulcerative colitis. They are most often called 5-ASAs, which is short for 5-aminosalicylic acid. 5-ASAs work on the lining of the gut to reduce inflammation by decreasing things that cause inflammation. It is also thought that mesalamine, the active ingredient in 5-ASAs, gets rid of oxygen-derived free radicals, which can cause cell death. 5-ASAs work better for ulcerative colitis than for Crohn's disease because ulcerative colitis affects only the lining of the colon, whereas Crohn's disease affects the deeper layers of the colon and/or small intestine.



What are the benefits of taking 5-ASA?

5-ASAs are the first choice to treat mild to moderate ulcerative colitis. It is used to bring you into remission and also keep you in remission. This is why it is called a maintenance medicine. 5-ASAs are very effective at reducing inflammation, which decreases your symptoms and prevents flares. When you take a 5-ASA regularly, it may help to protect you from developing colon cancer.

This type of medicine is safe to take for a long time. Most people who take 5-ASAs do not have any side effects. 5-ASAs work for about 75% of those with ulcerative colitis. People with Crohn's disease in the colon are more likely to feel relief of symptoms than those who have Crohn's disease only in the small intestine. Sadly, 5-ASAs do not prevent flares in the long run in Crohn's disease, and are not FDA approved for the treatment of Crohn's Disease. 5-ASAs do not work as well in treating severe forms of both Crohn's disease and ulcerative colitis.



What are the medicine names of 5-ASAs and how do I take a 5-ASA?

The generic name **mesalamine** is the active ingredient in several different brand name medicines such as **Asacol HD**[®], **Delzicol**[®], **Lialda**[®], **Apriso**[®], and **Pentasa**[®]. These medicines are all pills that should be taken with plenty of water. People who take Asacol HD[®], Delzicol[®], and Pentasa[®] often need to take several pills each day. Lialda[®] and Apriso[®] are easier to take because they require fewer pills daily, but sometimes they cost more depending on your insurance. All of the 5-ASA medicines work equally well when taken as directed. It is important to find the medicine that works best for you.

There are two forms of mesalamine made to be given per rectum: **Canasa**[®] (suppository) and **Rowasa**[®] (enema). These medicines treat distal inflammation (when the left side of the colon and/or the rectum is the only area affected). The enema works best if it can be held in the rectum as long as possible, ideally for up to 1 hour.

Balsalazide (Colazal®) and **olsalazine (Dipentum™)** are similar medicines that are pro-drugs of mesalamine. This means that after you take balsalazide or olsalazine, the medicine changes to mesalamine in the body. Because these medicines don't turn into mesalamine until they reach the large intestine, more of the medicine gets to the colon. Colazal® is a capsule that can be taken whole or the contents of the capsule can be sprinkled into applesauce if you have a hard time swallowing pills.

Sulfasalazine (Azulfidine®, Azulfidine EC®) is made from mesalamine combined with a form of sulfa. This medicine is a sulfa drug. You can get a generic form of sulfasalazine, which makes it less costly than the other 5-ASAs (\$30 compared to \$300). Sulfasalazine is slightly more effective than the other 5-ASAs; however, 10% to 15% of people have side effects and cannot take sulfasalazine. The most common side effect is a skin rash, which is an allergic reaction to the sulfa part of the medicine.



How quickly do 5-ASAs start to work and how long should I take a 5-ASA?

If you take the medicine regularly, your symptoms should start to improve in 2 to 4 weeks. If your inflammation is more severe, you may also need to take a 5-ASA as an enema or a suppository. Taking these along with the 5-ASA pills will help you get better more quickly. 5-ASAs work best if they are taken all of the time, not just when you have a flare. If you can tolerate the medicine without any side effects and it is helping to control your inflammation you can take the medicine on an on-going basis. Always talk to your doctor before taking a smaller dose of your medicine or if you plan to stop taking it.



Will I have to take medicines in addition to a 5-ASA to treat my ulcerative colitis or Crohn's disease?

People who suffer from moderate to severe forms of IBD may need to take other medicines in addition to a 5-ASA. If you develop a flare you may need a course of a steroid medicine such as prednisone or budesonide (Entocort®). Once the flare has settled down and you taper off of the steroid you may be able to take only a 5-ASA. Immunosuppressive drugs are frequently needed to treat more severe ulcerative colitis and Crohn's disease. The more flares you have, the more likely you will need to take an immunosuppressive medicine.



Is there anything I should avoid while taking a 5-ASA?

You should not take cardiac glycosides like digoxin when you are taking 5-ASAs. Be sure to tell all of your health care providers about all the medicines you are taking, including over-the-counter vitamins and herbal products.



Will I need to have any tests while I am taking a 5-ASA?

These medicines have rarely been shown to cause kidney problems (only 1 in 10,000 people). Your kidney function will be tested before you start taking the medicine, 3 months later, and then once yearly. Ask your doctor if NSAIDs (nonsteroidal anti-inflammatory drugs such as ibuprofen) are safe for you. NSAIDs taken with 5-ASAs can harm the kidneys.



What are the side effects of 5-ASAs?

5-ASAs generally cause very few side effects. The most common and less serious side effects of 5-ASAs include headache, abdominal pain, belching, nausea, diarrhea, and pharyngitis (sore throat). The enema and suppository form of mesalamine cause even fewer side effects. Signs that your body is not able to tolerate these medicines include cramping, severe abdominal pain, and bloody diarrhea, and sometimes fever, headache, or rash. If you have any of these symptoms after starting the medicine call your health care team right away. You may need to stop taking the medicine. Do not be alarmed; 5-ASAs may turn your urine to a brown-yellow color.

Sulfasalazine (Azulfidine[®], Azulfidine EC[®]) contains sulfa, and a common side effect of this medicine is an allergy to the sulfa. True allergic reactions include hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, and wheezing. Anaphylaxis (vascular shutdown) can occur but is rare. If you have an allergic reaction, stop taking this medicine and call your doctor, go to the emergency room, or call 911. If you know you are allergic or cannot take sulfa drugs, do not take sulfasalazine (Azulfidine[®], Azulfidine EC[®]). Another common side effect of sulfasalazine is headache. This is directly related to the starting dose of the medicine so it is common to start with a lower dose and then slowly increase to the needed dose. Enteric-coated sulfasalazine can reduce stomach upset but it costs more. Most people who cannot tolerate this medicine can still take other forms of 5-ASAs. Sulfasalazine (Azulfidine[®], Azulfidine EC[®]) can cause anemia, low white blood cell counts, and increased risk for infections. It is also known to reduce sperm counts in about 10% of men, which may affect fertility. Sperm counts return to normal after stopping the medicine. It is not known to cause birth defects.



What are the risks of taking a 5-ASA?

As noted above, 5-ASAs can cause kidney problems, but this is very rare. 5-ASAs may also make the varicella (chickenpox) vaccine more toxic. This is called Reye's syndrome and occurs in children. Children should never be given aspirin and 5-ASAs while they are ill with chickenpox or have just received the chickenpox vaccine.



What is the difference between 5-ASAs and over-the-counter NSAIDs?

Common over-the-counter NSAIDs like ibuprofen (Advil[®]) and naproxen (Aleve[®]) are used to treat pain. Prescription NSAIDs, such as oxaprozin (Daypro[®]), diclofenac sodium (Voltaren[®]), and naproxen (Anaprox[®] or Naprosyn[®]), to name a few, are used to decrease inflammation. These NSAIDs are absorbed into the bloodstream and work throughout the body. 5-ASAs also reduce inflammation, but they do not treat pain and they **only work in the bowel**. People who suffer from Crohn's disease and ulcerative colitis should avoid taking over-the-counter and prescription NSAIDs on a routine basis because they can irritate the lining of the GI tract, which can make their Crohn's disease and ulcerative colitis worse. In addition, people with IBD who routinely take 5-ASAs should not also take NSAIDs because taking them together may damage to the kidneys. If you are not taking a 5-ASA and you need to take an NSAID regularly for

another chronic medical condition, such as arthritis, ask your doctor about other medicines. Other options include acetaminophen (Tylenol[®]), etodolac (Lodine[®]), or Celebrex[®].

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Azathioprine/Mercaptopurine



What is azathioprine and how does it work?

Azathioprine (abbreviated AZA, brand name Imuran[®]) is a purine synthesis inhibitor used to treat rheumatoid arthritis (RA) or after a kidney transplant. It is also widely used for Crohn's disease and ulcerative colitis. Azathioprine prevents your body from making certain kinds of white blood cells that cause inflammation in the gut. It is an immunosuppressive medicine, which means it partially blocks the action of the immune system, but does not completely turn it off. While there are some side effects, most people do not get more infections when they take this medicine.



What is mercaptopurine?

Azathioprine is a pro-drug. This means that after you take azathioprine, it is changed in the body to the active form of the drug, which is 6-mercaptopurine. 6-Mercaptopurine (or mercaptopurine) is also called Purinethol[®] (brand name) and is abbreviated 6-MP. Whether you take mercaptopurine or azathioprine, both of these medicines work the same way to help your disease. Even though these medicines work the same, you cannot change one pill for the other because the dose of each medicine is different.



What are the benefits of taking azathioprine?

Azathioprine has been used for several years in people with IBD. If you have disease flares fairly often (uncontrolled inflammation in your gut), you may need several courses of prednisone. Prednisone works very well in the short-term to reduce inflammation and symptoms. Prednisone does not work to keep you in remission, and it has many side effects. This is why it is only used for acute flares. Azathioprine may be used if you cannot stop taking prednisone without your symptoms getting worse. Azathioprine can lessen the damage to the intestine in both ulcerative colitis and Crohn's disease, which can improve your health in the long-term. If you get better while taking azathioprine, you will avoid the side effects of prednisone, avoid the complications of untreated inflammation, and improve your quality of life.



How quickly does azathioprine work?

Azathioprine may take 2 to 4 months to work, so it is important to keep taking the medicine even though you may feel that it isn't helping. Azathioprine can be slow to work and it can also be slow to wear off. It works best when it is taken regularly. If you can tolerate azathioprine and it is helping to control your inflammation, you may continue to take it as long as it works for you. Always talk to your doctor before changing your dose or before stopping it.



How should I take azathioprine?

Take azathioprine with a full glass of water or with food to prevent stomach upset. Take this medicine exactly as it was prescribed for you. Azathioprine is usually given at a dose between

1.5 to 3 mg/kg daily. Many people start with a 50-mg dose. Do not take larger doses unless told to do so. If you have impaired kidney function, your dose of azathioprine will be decreased.

If you improve while taking azathioprine, you will take it for as long as you can. If you stop taking azathioprine, you can start it again anytime in the future, as long as you did not have side effects when you took it the first time. Even after not taking azathioprine for long periods, people who start the medicine again usually find that it works as well as it did the first time. This is not the case with other medicines, such as infliximab (Remicade[®]). Always talk to your doctor before changing your dose or if you plan to stop taking it.



May I take azathioprine with other medicines used to treat Crohn's disease and ulcerative colitis?

If you are already taking a 5-ASA medicine, azathioprine may be added so that you get better results from the two medicines working together. If an anti-TNF such as infliximab (Remicade[®]) has been added to your medicines, do not stop the azathioprine unless you discuss it with your doctor first. You may need to take both of these medicines if you have more severe inflammation. Recent studies suggest that people with early Crohn's disease or history of severe inflammation do better if they take infliximab (Remicade[®]) and azathioprine together. It is believed that taking azathioprine may help to prevent your body from making antibodies against the anti-TNF medicine, so that the anti-TNF works longer. Other immunosuppressive medicines, such as prednisone and budesonide (Entocort[®]), may also be taken with azathioprine. Remember that whenever you take more than one immunosuppressive medicine for a long time, your risk for infection and cancer increases. You and your doctor will consider the risks and the benefits and decide which plan is best for you.



Is there anything I should avoid while taking azathioprine?

Non-prescription products: Do not take any over-the-counter herbal products with echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including azathioprine.

Prescription medicines: Allopurinol is a medicine used to treat gout. Some people find that azathioprine works better for treating IBD if it is taken with allopurinol. However, you should not take allopurinol with azathioprine unless directed to do so because this can cause severe bone marrow suppression. This means your number of white blood cells is too low. Azathioprine used along with ACE inhibitors may cause low white blood cell counts. Azathioprine is not used if you have ever taken an alkylating agent for cancer chemotherapy such as cyclophosphamide (Cytoxan[®]). Do not take azathioprine with mercaptopurine or natalizumab. The use of azathioprine with anti-TNF medicines such as infliximab (Remicade[®]) should be directed and closely monitored by your doctor. Other prescription medicines may interact with azathioprine.

Be sure to tell your health care team about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, herbal products, as well as medicines prescribed by other doctors. Do not take a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.



Will I need to have any tests while I am taking azathioprine?

One-time blood test: In some people, azathioprine passes so quickly through the body that it does not work. In others, it passes too slowly and can build up and be harmful. Before you start taking azathioprine you will have a blood test called TPMT. This test will measure how quickly your body breaks down azathioprine. The result of this test will show if azathioprine is safe for you. If the blood test shows that the drug will pass too quickly, you may need to take allopurinol to slow down the breakdown of azathioprine. If you take allopurinol for this reason, you will take a lower dose of azathioprine. If another doctor prescribes allopurinol for you, please talk to your IBD doctor before you start taking it.

Regular blood tests: While you are taking azathioprine, you will need to have your blood tested on a routine basis to check your blood cell counts and your liver function. You will have a blood test when you start the medicine and then at weeks 2, 4, 8, and 12. If the results of these blood tests are normal, your blood will be drawn every 3 months from then on. Your dose of azathioprine may change based on the results of your blood tests. If your dose is changed, the time between your blood tests may also change. If you start taking allopurinol, you will need weekly blood tests for at least 4 weeks and then every 2 weeks for a couple of months. Ask your doctor about the results of your blood tests and what they mean.



What are the side effects of azathioprine?

Many people who take azathioprine do not have any side effects.

Allergic reaction: Allergic reactions are rare and usually happen right away. True allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (vascular shutdown) may occur but are very rare. If you have an allergic reaction, go to the emergency room or call 911. Stop taking azathioprine permanently if you have an allergic reaction to it.

Common side effects: You may have side effects such as nausea, vomiting, gastritis (inflammation in your stomach), fever, malaise (general sick feeling), diarrhea, low white blood cell count, low platelet count, liver toxicity, or muscle pain. You will be monitored closely for side effects and your dose may be adjusted based on the results of your blood tests. Be assured that if you cannot tolerate azathioprine the side effects will go away after you stop taking it. To reduce nausea, restarting at a lower dose and increasing it slowly may be helpful. Also, it may help to take the medicine before bed or divide the dose and take smaller doses of medicine at different times throughout the day. A change from azathioprine to mercaptopurine may be another option to help decrease side effects in some patients.

Uncommon side effects: Call your doctor if you develop severe upper abdominal or back pain. If this happens, you will have a blood test to rule out pancreatitis (inflammation of the pancreas). If you develop pancreatitis while you are taking azathioprine it will be stopped for good.



What are the risks of taking azathioprine?

The most common infections associated with azathioprine are from viruses that stay in your body and can be reactivated. Some examples are as follows.

Shingles: Shingles is caused by the re-activation of the virus that causes chicken pox, VZV. If you have had chicken pox, your doctor may check your antibody level against VZV to determine if you have antibody protection.

Cervical Cancer: Cervical cancer is caused by activation of the HPV virus, which is more likely in patients on azathioprine. Annual PAP smears are recommended for women who are taking azathioprine or 6-MP medicine.

Lymphoma: Because azathioprine is an immunosuppressive medicine there is a small risk for getting lymphoma, a type of cancer. However, it is not clear whether this risk is due to the medicine or to the IBD. You will be monitored closely while you are taking azathioprine. The risk for lymphoma in people who do not take azathioprine is about 1/10,000. In IBD patients taking azathioprine, it is about 4/10,000. As you can see, this means that there is a very small increase in your risk. The benefit of getting into remission and maintaining remission often outweighs this small increased risk for lymphoma. The risk may be higher in patients with new infections with Epstein Barr virus (EBV – the virus that causes mononucleosis). The risk appears lower in patients who have antibodies against EBV. Your doctor may test you for antibodies against EBV to determine your risk level. Tell your doctor right away if you notice any increase in pain, weight loss, or ongoing fevers you cannot explain. If any of these occur, blood tests or a CT scan may be needed. Be sure to tell your doctor if you have cancer now or if you have had it in the past.

Skin cancer: Azathioprine may also increase your risk for certain types of skin cancer. To protect yourself from getting skin cancer while taking azathioprine, avoid being in the sun and make sure to use sun block when you spend time outside. Also, do not use tanning beds. You will need to have a yearly skin exam by a dermatologist if you take azathioprine on a long-term basis.

Infections: Azathioprine can increase your risk for infections, particularly viruses that stay in your body like EBV, VZV, and HPV. This risk is higher with azathioprine. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These vaccines include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever**. Azathioprine can also increase the risk for having shingles. If you are older than 60, you should get a shingles vaccine 6 weeks **BEFORE** starting azathioprine. If you have never had chickenpox, you should get a chickenpox vaccine 6 weeks **BEFORE** starting azathioprine.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Methotrexate



What is methotrexate?

Methotrexate (abbreviated MTX) is used to treat rheumatoid arthritis, psoriasis, and several different kinds of cancer. It is also used to treat Crohn's disease. It has been studied less as a treatment for ulcerative colitis, although small studies suggest that it works well. Methotrexate is an anti-folate drug, which means it blocks the breakdown of folic acid. Methotrexate was first used in high doses to treat leukemia. High doses are needed to kill cancer cells, but only low doses are needed to treat IBD. Low-dose methotrexate (5–25 mg weekly) used to treat Crohn's disease does not kill cells, but instead reduces inflammation. It keeps your body from making certain kinds of white blood cells that cause inflammation in the gut. Methotrexate is an immunosuppressive medicine, which means it partially blocks the action of the immune system but does not completely turn it off. While there are some side effects, most people do not get more infections when they take this medicine.



What are the benefits of taking methotrexate?

If you have disease flares fairly often (uncontrolled inflammation in your gut) you may need several courses of prednisone. Prednisone does not work to keep you in remission, and it has many side effects. This is why it is only used for acute flares. Methotrexate may be used if you cannot stop taking prednisone without your symptoms getting worse. You may also take methotrexate if you cannot take azathioprine or mercaptopurine, two other medicines often used to treat Crohn's disease and ulcerative colitis. Methotrexate can lessen the damage to the intestine, which can improve your health in the long-term. If you get better while taking methotrexate, you will avoid the side effects of prednisone, avoid the complications of untreated inflammation, and improve your quality of life. Occasionally, methotrexate will be combined with other medicines (like Remicade or Humira) to control active disease.



How quickly does methotrexate work?

Methotrexate may take 4 to 8 weeks to work, so you need to keep taking it even though you may feel that it isn't helping. It can be slow to work and it can also be slow to wear off. Methotrexate works best when it is taken regularly. If you can tolerate methotrexate and it is helping to control your inflammation, you may continue to take it as long as it works for you. Always talk to your doctor before changing your dose or before stopping it.



How do I take methotrexate?

Methotrexate is hazardous because it is a teratogenic agent (causes birth defects). Therefore, there are safety measures to follow when handling it and when getting rid of it.

You may take methotrexate either as a subcutaneous injection (a shot given under the skin) or as tablets that you swallow. The oral dose is not as well absorbed as the injection dose but may be tried in patients doing well on injections. A common starting dose is 25 mg. If this dose works, it may be lowered to 15 mg for ongoing therapy. The lower dose does not work for

everyone and some people stay on the 25-mg injection in order to improve. If you have impaired kidney or liver function your dose will be decreased.

If you improve while taking methotrexate, you will take it for as long as you can. If you stop taking methotrexate, you can start taking it again anytime in the future, as long as you did not have side effects when you took it the first time. Even after not taking methotrexate for long periods, people who start taking the medicine again, usually find that it works as well as it did the first time. This is not the case with other medicines, such as infliximab (Remicade[®]). Always talk to your doctor before changing your dose or if you plan to stop taking it.



May I take methotrexate with other medicines used to treat Crohn's disease and ulcerative colitis?

You will need to take 1 mg of folic acid daily (a folate supplement) while taking methotrexate. If you are already taking a 5-ASA medicine, methotrexate may be added so that you get better results from the two medicines working together. If an anti-TNF such as infliximab (Remicade[®]) has been added to your medicines, do not stop taking the methotrexate unless you discuss it with your doctor first. This combination of methotrexate and an anti-TNF may be prescribed if you have more severe inflammation. One potential benefit of taking methotrexate and an anti-TNF is that methotrexate may lower the risk of your body developing antibodies to the anti-TNF medicine. Other immunosuppressive medicines such as prednisone and budesonide (Entocort[®]) may also be taken with methotrexate. Remember that whenever you take more than one immunosuppressive medicine for a long time, your risk for infection or cancer increases. You and your doctor will consider the risks and the benefits and decide which plan is best for you.



Is there anything I should avoid while taking methotrexate?

Non-prescription products: Do not drink alcohol while taking methotrexate because the two together can cause permanent liver damage. Do not take more than 3 grams per day (two 500 milligram tablets three times per day) of acetaminophen (Tylenol[®]) including other acetaminophen containing products while taking methotrexate. Do not take any over-the-counter herbal products with echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including methotrexate.

Prescription medicines: Severe (sometimes fatal) bone marrow suppression (low blood cell counts), aplastic anemia (the bone marrow does not make enough blood cells), and gastrointestinal damage, have been reported when methotrexate (usually in high doses) is taken along with certain nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen.

Do not take methotrexate with acitretin, cyclosporine, eltrombopag, natalizumab, salicylates, sulfonamide derivatives, trimethoprim, and uricosuric agents. Some prescription medicines, especially antibiotics may interact with methotrexate. **Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not take a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need any tests while I am taking methotrexate?

While you are taking methotrexate you will need to have your blood tested on a routine basis to check your blood cell counts and your liver and kidney function. You will have a blood test when you start the medicine and then at week 2, 4, 8, and 12. If the results of these blood tests are normal, your blood will be drawn every 3 months from then on. Your dose of methotrexate may change based on the results of your blood tests. If your dose is changed, the time between your blood tests may also change. Ask your doctor about the results of your blood tests and what they mean. Be sure to tell your doctor if you are taking any other medicines because they may affect the level of methotrexate in your body.



What are the side effects of methotrexate?

Most patients who take methotrexate do not have any side effects.

Allergic reaction: Allergic reactions are rare and usually happen right away. True allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (vascular shutdown) may occur but are very rare. If you have an allergic reaction, go to the emergency room or call 911. Stop methotrexate permanently if you have an allergic reaction.

Uncommon side effects: Nausea, vomiting, and fatigue occur most often and usually on the day after injection. Other side effects include nausea, vomiting, diarrhea, loss of appetite, elevated liver enzyme levels, fatigue, hair loss, and photosensitivity (eyes sensitive to sunlight). If you have kidney disease, side effects are more likely. Lowering the dose, taking the medicine in the evening, or dividing the dose into three smaller doses (one on Monday, one on Wednesday, and one on Friday) may help to reduce the side effects. Folic acid (1 mg daily) can reduce nausea, vomiting, and stomach upset. Some people take an anti-nausea medicine, like Zofran just before the injection to prevent nausea and vomiting. Once your body is used to taking methotrexate, these symptoms may go away.



What are the risks of taking methotrexate?

Mouth sores: If you get sores inside your mouth or on your lips, call your doctor right away. This means that the dose of methotrexate is too high. You will stop taking it and start again at a lower dose. Sometimes a medicine called leucovorin is given to reverse the effects of methotrexate and to help the sores heal more quickly.

Liver damage: Liver enzymes spill into the blood if liver cells are damaged. These levels increase in a small number (8%) of people who take methotrexate. This is related to the buildup of methotrexate in your body over time. You should not take this medicine if you have chronic liver disease. Alcoholism, obesity, advanced age, and diabetes may increase your risk for liver problems when you are taking methotrexate.

Kidney damage: This usually only occurs when high doses of methotrexate are taken. Your kidney function will be checked by routine blood tests while you are taking methotrexate.

Bone marrow suppression: This occurs in a small number (5%) of people taking methotrexate. The result is a low blood cell count. This increases your risk for infections and bleeding.

Skin conditions: There is a rare risk of developing potentially fatal skin conditions, including Steven's-Johnson syndrome and toxic epidermal necrolysis, when you take methotrexate. Tell your doctor right away if you notice any new rash. Also, your skin may become more sensitive to light when you take methotrexate. Remember to use sunblock when you spend time outside and do not use tanning beds.

Lung inflammation: If you have chest pain, cough, difficulty breathing, or fever while you are taking methotrexate, call your doctor right away. A chest X-ray and CT scan may be needed to check your lungs. Prednisone may be used to treat lung inflammation.

Lymphoma: Because methotrexate is an immunosuppressive medicine there is a small risk for getting lymphoma, which is a type of cancer. However, it is not clear whether this risk is due to the medicine or to the IBD. You will be monitored closely while you are taking methotrexate. Tell your doctor right away if you notice any increase in pain, weight loss, or ongoing fevers that you cannot explain. If any of these occur, blood tests or a CT scan may be needed. Be sure to tell your doctor if you have cancer now or if you have had it in the past.

Infections: Methotrexate can increase your risk for infections. The risk is higher if you take another immunosuppressive medicine with methotrexate. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These vaccines include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever**. Methotrexate can also increase your risk for having shingles. If you are older than 60, you should get a shingles vaccine 6 weeks before starting to take methotrexate. If you have never had chickenpox, you should get a chickenpox vaccine 6 weeks **BEFORE** starting to take methotrexate.



Can I take methotrexate if I want to get pregnant?

NO WAY!! Methotrexate is a Category X medicine, which means it should **NEVER** be used during pregnancy or the 6 months before trying to become pregnant. There is a very high risk of birth defects if you use methotrexate while you are pregnant. If you think you are pregnant, stop taking methotrexate **right away** and call your doctor so that you can have a high-risk pregnancy visit. Special safety measures are always needed when using methotrexate during childbearing years. Double contraception is required while taking this medicine. This means that **both the man and the woman** need to use birth control. For example, condoms are used by the man and birth control pills or an IUD are used by the woman. This is also true for couples when only the man is taking methotrexate, because this drug can affect the sperm. Men who take methotrexate should also stop taking the medicine **6 months** before trying to conceive with their partner. All persons (male and female) must continue to use birth control for **at least 6 months** after stopping

methotrexate to be certain that the medicine is completely out of the body. Breast-feeding is also not safe while taking methotrexate.

Dosing Chart

| Methotrexate dose | Number of 2.5 mg tablets | ml or units in an insulin syringe |
|--------------------------|---------------------------------|--|
| 10 mg once a week | 4 tablets | 0.4 ml or 40 units in insulin syringe |
| 15 mg once a week | 6 tablets | 0.6 ml or 60 units in insulin syringe |
| 20 mg once a week | 8 tablets | 0.8 ml or 80 units in insulin syringe |
| 25 mg once a week | 10 tablets | 1.0 ml or 100 units in insulin syringe |

How to Inject Methotrexate

1. Gather needed items: vial of medicine, syringe, and alcohol pad
2. Wash and dry your hands.
3. Clean the top of the vial with the alcohol pad.
4. Use the alcohol pad to wipe the area you will inject, either the top of the thigh or belly.
5. Remove the cap from the needle.
6. Pull the plunger until the syringe has the same volume of air as the medicine you are going to give.
7. Put the needle into the vial of medicine and push the plunger down (to put air into the vial).
8. Turn the bottle over and slowly pull down the plunger to your dose. See chart above.
9. Check for air bubbles and flick them out if needed.
10. Pull the needle out of the vial.
11. With your non dominant hand, pinch the skin around the area you cleaned.
12. With your dominant hand, insert the needle straight into the skin.
13. Bring your non dominant hand over to support the syringe and with your dominant hand, push the plunger all the way down to inject the medicine.
14. Pull the needle straight out.
15. Discard the needle/syringe unit into your puncture proof Sharps container.
16. Wash and dry your hands.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse or pharmacist.

Prednisone



What is prednisone?

Prednisone is a corticosteroid medicine that is often referred to as a steroid. This is not the type of steroid certain sports players take to increase their muscles. Prednisone is the type of steroid that reduces inflammation. Every day our bodies naturally make cortisone, which is a steroid that is released in response to stress. This daily amount of cortisone our bodies make is equal to about 5 mg of prednisone. One of the many jobs of cortisone is to prevent the immune system from causing inflammation in the body. Prednisone is a medicine that is very similar to cortisone. It is an immunosuppressive medicine, which means it partially blocks the action of the immune system, but does not completely turn it off. While there are some side effects, most people do not get more infections when they take this medicine.

Prednisone is used to treat many different disorders, such as allergies, asthma, rashes, arthritis, lupus, psoriasis, as well as Crohn's disease and ulcerative colitis.



What are the benefits of taking prednisone?

Every time you have a severe flare your risk for complications increases. In the short term, prednisone will quickly prevent your flare from getting so out of control that you will need to be in the hospital or have surgery. Prednisone reduces symptoms and brings on remission for most people (75% to 80%). The results from taking prednisone can be so good that you might want to continue taking it longer than you need it. However, prednisone will not keep you in remission. Unlike most IBD medicines, the longer you take steroids, the less they will work. Taking prednisone for a long time or taking many short courses for a long time increases your risk for serious side effects. This risk may be greater than any benefit you get from controlling the inflammation. In addition, steroids such as prednisone do not work as well the longer you take them. Prednisone is only used as a quick treatment for disease flares while you start a maintenance medicine, with the goal of tapering off the prednisone as soon as possible.



How quickly does prednisone work?

Prednisone works quickly and many people notice improvement in their symptoms by the second day. It generally takes about 5 to 7 days to reach full effect. If you are not getting better, you may have severe inflammation or an infection of the intestine, like *Clostridium difficile* (*C. diff.* for short). People with Crohn's disease and ulcerative colitis are more likely to get this infection. If you do not get better, call your doctor. A stool test is often needed to see if you have this infection before you start prednisone.



How should I take prednisone?

Take prednisone after meals or with food or milk to protect your stomach. Most people take it in the morning because it tends to keep them awake at night if taken later in the day. Prednisone is generally taken at the highest dose (40–60 mg for adults or 1–2 mg/kg for children) for 1 to 2

weeks to relieve the symptoms. Then you will decrease the dose by 5 to 10 mg every 1 to 2 weeks for about 4 to 12 weeks. This is called a taper. The speed at which you taper depends on the side effects, the severity of the flare, and how quickly your maintenance medicine takes effect. Do not change your dose without talking to your doctor first because it is hard to know how well the medicine is working if the dose changes. If you need to be on prednisone longer than 12 to 16 weeks, you probably need to change to a different maintenance medicine. Because of the risk for serious side effects, you and your doctor will work together so you can avoid taking prednisone longer than you have to.



Is there anything I should avoid while taking prednisone?

Non-prescription products: Limit alcohol and caffeine to less than 1 to 2 drinks of each daily while taking prednisone. Do not take any over-the-counter herbal products with echinacea, cat's claw, or alfalfa because these can reduce the effect of all immunosuppressive medicines, including prednisone. You also need to avoid St. John's wort as it may decrease prednisone levels.

Prescription medicine: Many medicines interact with prednisone. Talk with your doctor about your current medicines and whether they are safe to take with prednisone. Common medicines to avoid while taking prednisone include antacids and "-mycin" antibiotics such as clarithromycin and erythromycin. Azithromycin is a "-mycin" antibiotic that is safe to take with prednisone. The fluoroquinolone or "-oxacin" antibiotics such as levofloxacin or ciprofloxacin cause an increased risk for tendon rupture and if possible should not be taken with prednisone. Do not take prednisone with aprepitant, maraviroc, natalizumab, neuromuscular blocking agents, or somatropin. **Be sure you tell your doctor about all the prescriptions and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not take a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need to have any tests while I am taking prednisone?

Prednisone may cause a decrease in bone density, which in turn may lead to osteoporosis. This can occur even in very young people who take prednisone. If you have taken prednisone for at least 3 months total in your life, you should have a bone density scan (also called a DEXA scan) to be sure your bones are healthy. It is a good idea to take a calcium plus vitamin D supplement while you are taking prednisone. If you get osteoporosis you may need to take medicines called bisphosphonates. Regular weight-bearing exercise such as jumping, jogging or lifting weights will also help protect against bone loss. Talk to your doctor about which type of exercise is right for you.



What are the side effects of prednisone?

Allergic reaction: It is unlikely you will have an allergic reaction to prednisone because steroids are the medicines that work best to treat allergies. However, if you do have allergy-like

symptoms while taking prednisone you may be allergic to one of the other things in the medicine. True allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (vascular shutdown) are rare. If you have an allergic reaction, go to the emergency room or call 911.

Common side effects: These include feeling hungry a lot of the time, weight gain, trouble falling or staying asleep (insomnia), mood changes (anxiety, crying, bad temper, anger), blurry vision, increased body fat (especially in the abdomen and the face), swelling of legs and face, slow wound healing, acne (can be severe), dry or thinning skin, easy bruising, increased sweating, increased blood sugar (especially in people with diabetes), increased facial hair, menstrual problems, impotence, and loss of interest in sex. **Prednisone can cause decreased growth rate in children.** Prednisone should only be used in children if the benefits of treatment outweigh this serious risk.

Less common but more serious side effects: These include dangerously high blood pressure (which may cause severe headache, blurred vision, buzzing in the ears, anxiety, confusion, chest pain, shortness of breath, uneven heartbeats), extreme mood swings, depression, headache, trouble falling or staying asleep (insomnia), personality changes, dizziness, easy bruising, stretch marks, flushing, very slow wound healing, low level of potassium (symptoms include confusion, uneven heart rate, extreme thirst, increased urination, leg cramps, muscle weakness or limp feeling), pancreatitis (inflammation of the pancreas that may cause severe pain in your upper stomach spreading to your back, nausea and vomiting, fast heart rate), very high blood sugar, osteoporosis, cataracts, glaucoma.



What are the risks of taking prednisone?

Adrenal crisis: Never stop taking prednisone all of a sudden without tapering because this can cause your body to go into what is called an adrenal crisis. That is why you taper off prednisone slowly. Your adrenal glands normally make a certain amount of cortisone every day. But, when you take prednisone your body senses that it no longer has to make any additional cortisone. Therefore, your body stops making cortisone altogether. If you slowly decrease the dose of prednisone, your body will sense that it must start to make cortisone again. If you stop without tapering, you will have no cortisone and your body can go into an adrenal crisis, which is a very serious condition. You are at increased risk for an adrenal crisis during physical stress such as infection, injuries, or after surgery. Symptoms of adrenal crisis include a sudden sharp pain in the legs, lower back, or abdomen, severe vomiting and diarrhea (which can cause you to be dehydrated), low blood pressure, fainting, low blood sugar, confusion, psychosis, slurred speech, severe lack of energy, seizures, and fever.

Prednisone can make other medical problems worse. Be sure to tell your doctor about all of your medical conditions because prednisone can make many of these worse and harder to manage. These include diabetes, osteoporosis, high blood pressure, congestive heart failure, myasthenia gravis (a muscle disorder), glaucoma or cataracts, tuberculosis, herpes infection of the eyes, liver disease (such as cirrhosis), thyroid disorders, kidney disease, stomach ulcers, depression, and mental illness. Prednisone can also affect the results of certain blood tests, such as liver function tests and blood count.

Carry an ID card or wear a medical alert bracelet stating that you are taking prednisone, in case of emergency. Remember that your body stops making cortisone when you've been taking prednisone. If you have a serious illness, an injury, or surgery, your body normally releases larger amounts of cortisone. This means you will need larger doses of prednisone to fully heal and recover. Be sure to tell every doctor, dentist, or emergency care provider if you are taking a steroid medicine or have taken steroids in the past year.

Infection: Prednisone can cause an infection you already have to get worse or it can bring back a recent infection. Of all the medicines for IBD, it is the most likely to be associated with increased infections. This risk is higher if you are taking another immunosuppressive medicine while taking prednisone. **You should not take prednisone if you have a fungal infection.** Prednisone can also increase the risk for shingles. Call your doctor right away if you are exposed to chicken pox or measles. These conditions can be serious or even fatal in people who are taking a steroid medicine. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever.**

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Entocort[®], Uceris[®]



What is budesonide (Entocort[®], Uceris[®])?

Budesonide is a steroid medicine. It is often called by its brand name Entocort[®]. This is not the type of steroid certain sports players take to increase their muscles. Entocort[®] is the type of steroid that reduces inflammation. Every day our bodies naturally make cortisone, which is a steroid released in response to stress. One of the main jobs of cortisone is to prevent your body's immune system from reacting and causing inflammation. Entocort[®] is a medicine that is similar to cortisone. Entocort[®] is also a medicine in the same class as prednisone. Both Entocort and prednisone are often used to treat Crohn's disease and ulcerative colitis. Both work to partially block the immune system. Entocort[®] just works in the bowel, which is very different from prednisone, which can affect the whole body. Entocort[®] is mostly used to treat Crohn's disease. Uceris is released into the colon, so it is used to treat Ulcerative Colitis. An inhaled form is used to treat allergic rhinitis (stuffy nose from allergies) and asthma.



What are the benefits of taking budesonide (Entocort[®], Uceris[®])?

Budesonide is used to treat mild to moderate flares of Crohn's disease. Budesonide has fewer side effects than prednisone, because it becomes inactive once it is absorbed by the body. For this reason, budesonide can be a good choice to control disease flares for people who cannot tolerate prednisone. It works for some patients to reduce symptoms and cause a remission. The drawback is that it works less well the longer you use it. For this reason, budesonide is generally used for 3 months or less. One benefit of budesonide is that it causes less bone loss than prednisone. The reason budesonide has fewer side effects is because as soon as it is absorbed into the body it is changed into an inactive form.



How quickly does budesonide work?

Budesonide works pretty quickly and most people notice their symptoms are better within the first week. If you find that budesonide is not working, it may mean that you have very severe inflammation or an infection of the intestines like *Clostridium difficile* (C. diff. for short). People with Crohn's disease and ulcerative colitis are at risk for getting this infection. If you do not get better, call your doctor. A stool test may be needed to see if you have this infection.



How should I take budesonide?

Generally, budesonide is used to treat disease flares while you start taking a maintenance medicine. Remember that budesonide usually does not work as well the longer you take it; however, some people can stay in remission for a longer time when they take budesonide. When you take budesonide, take the pills in the morning and swallow the pills whole – do not crush or chew them. With Entocort[®], you will usually start at 9 mg per day and then slowly taper your dose to 6 mg and then 3 mg so that at the end of 3 months you will not be taking the medicine. With Uceris[®], patients often stop the medicine without a taper once their maintenance medicine is effective.



Is there anything I should avoid while taking Entocort®?

Non-prescription products: Do not eat grapefruit or drink grapefruit juice while taking budesonide because it makes budesonide less effective. Do not drink more than 1 to 2 drinks of alcohol daily. Do not take any over-the-counter herbal products with echinacea or cat's claw because these reduce the effect of all immunosuppressive medicines, including Entocort®.

Prescription medicine: There are many prescription medicines that interact with budesonide. Ask your doctor if your current medicines are safe to take with budesonide. More common medicines to avoid while taking budesonide include antacids. **Be sure to tell your doctor every prescription and over-the-counter medicine you are taking. These include vitamins and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need to have any tests while I am taking budesonide?

Budesonide has a smaller risk than prednisone for causing bone loss that may lead to osteoporosis. However, if you have taken budesonide or other steroids for a long period of time, you will have a bone density scan (DEXA) to be sure that your bones are healthy.



What are the side effects of budesonide?

Allergic reaction: It is unlikely you will have an allergic reaction because steroids are the medicines that work best to treat allergies. However, if you do have allergy-like symptoms while taking budesonide you may be allergic to one of the other things in the medicine. True allergic reactions such as hives, swelling of the face, lips, or tongue, shortness of breath, tightness of the chest or throat, wheezing, and anaphylaxis (vascular shutdown) are rare. If you have an allergic reaction, go to the emergency room or call 911.

Uncommon side effects: Side effects are not common with budesonide but may include headache, nausea, diarrhea, respiratory tract infection, sinus infection, joint pain. Budesonide may slow growth in children and therefore should only be used if the benefits of treatment outweigh this serious risk.

Rare side effects: These include weight gain, fatigue, muscle weakness, facial rounding, fragile or thin skin, dizziness, throat irritation, and cataract.



What are the risks of taking budesonide?

Adrenal crisis: This risk is much higher with prednisone but it is still possible with budesonide.

Budesonide may make other medical problems worse. Again, this is not as likely to happen as with prednisone, but it is still possible. It is important to tell your doctor about all of your medical conditions because budesonide may make other medical conditions worse.

Taking budesonide may increase your risk for infections. This risk is higher if you are taking another immunosuppressive medicine while taking budesonide.

You need to have a working thermometer at home to check for a fever whenever you are sick. If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever.**

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Anti-Tumor Necrosis Factor Antibodies (Anti-TNFs)



What are anti-TNFs and how do they work?

Anti-TNF medicines are antibodies that bind to tumor necrosis factor (TNF). Antibodies are proteins made by our bodies to help get rid of foreign things that get into our bodies and can harm us. TNF is also a protein and it is made by our bodies to help cause inflammation. When antibodies are bound to TNF, the TNF cannot cause inflammation in the intestine. These antibodies can also block cells from making TNF. Anti-TNF medicines are in the category of biologic agents or biologics. They are immunosuppressive medicines. This means that they partially block the action of the immune system, but do not completely turn it off. While there are some side effects, most people do not get more infections when they start taking this medicine.



What is tumor necrosis factor (TNF) and how does it work?

TNF is a protein made by the immune system that helps cause inflammation in the body. TNF works by getting other immune proteins and immune cells to come to the area of the body where they are needed to fight infection or cancer. TNF can also be made by the body and work against the body's own cells. This is called an autoimmune reaction.



What are antibodies and how do they work?

Antibodies are proteins made by the immune system. They are found in the blood and in other body fluids. The job of antibodies is to find, stick to, and work against harmful bacteria, viruses, and proteins. Antibodies make these proteins inactive by attaching to certain places (antigens) on their surface. The anti-TNF antibodies are made in a lab to do a specific job in the body.



What are the names of anti-TNF medicines?

There are four anti-TNF medicines used to treat Crohn's disease and ulcerative colitis: infliximab (**Remicade**®), adalimumab (**Humira**®), and certolizumab pegol (**Cimzia**®), and golimumab (**Simponi**®)

Remicade® is used to treat Crohn's disease in adults and children and to treat ulcerative colitis in adults. It is also used to treat rheumatoid arthritis, ankylosing spondylitis, and psoriasis. It is given through an intravenous (IV) line in three doses. The second and third doses are given 2 weeks and 6 weeks after the first dose. Induction therapy refers to this initial series of three infusions. Then, maintenance treatment is needed every 8 weeks. The dose and time between doses may be changed to get the best response.

Humira®, like Remicade®, is used to treat rheumatoid arthritis, Crohn's disease, and ulcerative colitis. It is also used to treat psoriasis, juvenile arthritis, and ankylosing spondylitis. It is given as a shot just under the skin (subcutaneous injection). It comes as a single dose in a pre-filled syringe or pen. You can learn to give it to yourself at home. The first dose is 160 mg (4 shots, 40

mg each) and then 80 mg (2 shots, 40 mg each) at 2 weeks, and then 40 mg (one shot) every 2 weeks for maintenance. About ½ the patients will need 40mg once weekly. Like Remicade[®], the dose and times between doses may be changed to get the best response.

Cimzia[®] is only used to treat Crohn's disease. The first dose is given as a shot just under the skin (subcutaneous injection) of 400 mg (2 shots, 200 mg each) to start and then repeated at weeks 2 and 4. The maintenance dose is 400 mg (2 shots, 200 mg each) every 4 weeks. Cimzia[®] comes in two forms: 1. powder that needs to be mixed with saline (sterile salt water) and given by a health professional; 2. liquid in pre-filled syringes that you can give to yourself.

Simponi[®] is the newest anti-TNF medicine. It is used for ulcerative colitis, psoriasis and rheumatoid arthritis. Simponi[®] is given as a shot under the skin (subcutaneous injection) of 200mg (2 shots, 100mg each) initially and then 100mg (1 shot) 2 weeks later. The maintenance dosing is 100mg (1 shot) every 4 weeks. Simponi[®] is dispensed in 2 different syringe types: 1. a pre-filled syringe which is injected in the typical manner under your skin; 2. An "auto-injector" that hides the needle and allows you to inject the medicine by pressing a button while in contact with your skin.



What are the benefits of taking an anti-TNF?

If you often have flares (uncontrolled inflammation in your intestine) you may need repeated courses of prednisone. Prednisone works very well in the short-term for reducing inflammation and easing your symptoms; however, it has many side effects and is not healthy to take long-term. You are 3 times more likely to require surgery if you take repeated course or use prednisone long-term. If you cannot tolerate or have not gotten a lot better with azathioprine or mercaptopurine you may need to take an anti-TNF. If you respond to anti-TNFs, you will have the benefit of not needing to take prednisone for a long period of time. You will also avoid the complications of inflammation that can lead to surgery. Anti-TNFs can improve your quality of life by controlling your symptoms. About 60% to 70% of patients who take these medicines notice that their symptoms decrease and their test results improve (endoscopy and blood tests measuring inflammation). Up to 40% of patients will be in remission (back to normal) by 6 months. If you do get better or reach remission there is a good chance that you will remain free of symptoms for up to 1 year.



How quickly do anti-TNFs start to work?

It takes time to measure the full effect of anti-TNFs: 6 weeks for Remicade[®] and 3 months for Humira[®], Cimzia[®], and Simponi[®]. Anti-TNFs work best if taken for the long-term. If you are able to tolerate the anti-TNF and it is helping to control your disease you may need to continue taking it. Always talk to your doctor before changing the timing or doses of your medicine or before stopping the medicine.



May I take an anti-TNF with other medicines used to treat Crohn's disease and ulcerative colitis?

Clinical research studies have suggested that people with Crohn's disease or Ulcerative colitis do better if they take Remicade[®] and azathioprine together. You may take these two medicines if you have more severe disease. It is believed that azathioprine helps to prevent your body from making antibodies directed against the anti-TNF medicine. This means you may benefit from taking an anti-TNF longer. Other immunosuppressive medicines such as prednisone, budesonide (Entocort[®]), azathioprine (Imuran[®]), mercaptopurine (Purinethol[®]), or methotrexate can be taken along with an anti-TNF as well.



Is there anything I should avoid while taking an anti-TNF?

Non-prescription products: Do not take any over-the-counter herbal supplement with echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines, including anti-TNF medicines.

Prescription medicines: Do not take abatacept, anakinra, natalizumab, vedolizumab, or riloncept with anti-TNF medicines. Other prescription medicines may interact with anti-TNFs. **Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need to have any tests while I am taking an anti-TNF?

You will be asked if you have any side effects while you are taking an anti-TNF. Your doctor will often monitor your inflammation with a blood marker called CRP to make sure the anti-TNF drug is working. If your CRP goes up, (a marker of inflammation), your doctor may check the level of the anti-TNF drug in your body to see if your dose needs to be adjusted.



What are the side effects of anti-TNFs?

Most people who take anti-TNFs don't have any side effects.

Allergic reaction: An allergic reaction right away when you start taking an anti-TNF is rare. True allergic reactions such as shortness of breath, tightness of the chest or throat, wheezing, hives, and anaphylaxis (severe shock) are also rare. If you have these symptoms, go to the emergency room or call 911. You will also stop taking that medicine but you may switch to another anti-TNF. Let your doctor know if you are sensitive to latex because the needle cover of the pre-filled syringe contains dry natural rubber (made from latex).

Infusion reaction: You may have an intravenous (IV) infusion-related reaction, which is a side effect that occurs within 2 hours of the start of an infusion of Remicade[®]. Symptoms include headaches, being lightheaded, joint and muscle aches, rash, flushing, and nausea. You may need to take Benadryl[®], Tylenol[®], and/or prednisone before your infusion to decrease these reactions. Taking this medicine in a shot can cause a reaction, but it is less common than when taking it as an IV infusion. In 2% to 5% of people who take Humira[®], Cimzia[®], or Simponi[®], the skin can

become swollen, red and painful where the shot is given. These reactions can be reduced by taking Tylenol® as well as cooling the area with an ice pack before the shot is given.

Somewhat common side effects: Other side effects that have been reported are headache, fatigue, joint pain, nausea, diarrhea, abdominal pain, urinary tract infection, upper respiratory infection, and sinusitis (sinus infection). Antinuclear antibodies and antibodies to double-stranded DNA may also develop, which means that the body is having an autoimmune reaction to the medicine.



What are the risks of taking an anti-TNF?

Resistance: There is a risk that your immune system may make antibodies against the medicine. If this occurs, you will stop taking the medicine because the anti-TNF will not work as well or it may not work at all.

Infections: Anti-TNFs can increase your risk for infections, mostly pneumonia, tuberculosis, and serious fungal infections like histoplasmosis. This risk is higher if you take another immunosuppressive medicine along with an anti-TNF. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

- **Pneumonia** this is the most common serious infection in patients on anti-TNF medicines. Your doctor will recommend a pneumonia vaccination if you take an anti-TNF medicine.
- **Tuberculosis (TB)** is a very serious bacterial infection. You are at higher risk for getting TB while taking an anti-TNF. If you've been exposed to TB in the past it can become active again when you take an anti-TNF. Before starting to take an anti-TNF you will have a skin test and you may have a chest x-ray to be sure you don't have TB. Tell your doctor if you have any history of being around someone with TB.
- **Hepatitis B** can get worse during anti-TNF therapy. Before starting to take anti-TNF you will have a blood test to be sure you do not have active hepatitis B infection and to see if your immune system already has the ability to fight off hepatitis B. It is a good idea to get the hepatitis B vaccine if you have not already had it.
- **Listeria:** You also have increased risk for getting an infection called listeria. Listeria comes from eating imported soft cheeses that are not clearly labeled as pasteurized. Examples of soft cheese include Brie, Camembert, feta, goat, Limburger, Neufchatel, and queso fresco. Cheeses made in the United States are made from pasteurized milk, which is the heating process that should kill bad bacteria. Hard cheeses such as cheddar or processed cheeses such as cottage cheese or yogurt are less likely to have bacteria that can make you sick. Listeria has also been found on some fruits and vegetables in the United States. Wash fruits and vegetables well before slicing them or eating them.

Lymphoma and other cancers: Because anti-TNFs suppress your immune system there is a small risk for getting lymphoma, which is a type of cancer. However, it appears that this risk is largely due to azathioprine use or to the inflammation of IBD itself. You will be closely monitored while you are taking an anti-TNF. The rate of lymphoma for people who take anti-TNFs for longer than 10 years is 7 in 1,000 people. This means there is a small increase in risk for having lymphoma. The risk may increase if you are taking azathioprine or 6-MP in addition to an anti-TNF or if you have a history of chronic obstructive pulmonary disease (COPD). You should call your doctor **right away** if you notice any increase in pain, weight loss, or fevers that you cannot explain. If this occurs, blood testing or CT scanning may be done. Tell your doctor if you have cancer or COPD now, or if you had either in the past.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever.**

Other risks: If you have moderate to severe congestive heart failure (), you should not take anti-TNFs. People with multiple sclerosis, seizure disorder, or a blood disorder such as a low blood count, also should not take anti-TNFs. It is rare, but some people get acute coronary syndrome, elevated liver enzymes (especially if the anti-TNF is used with methotrexate), low blood count, or serious skin conditions such as erythema multiforme from these medicines. Drug-induced lupus-like syndrome is also rare. If you get joint and muscle pain along with fatigue and a skin rash, call your doctor right away. Serum sickness-like reaction includes rash, welts (wheals), joint pain, fever, malaise, enlarged lymph nodes and should also be reported right away.

University of Michigan Infusion Centers – Remicade infusions are given in our outpatient clinics at the following locations:

- 1) East Ann Arbor Infusion Clinic located in the East Ann Arbor Health Center
4260 Plymouth Road, Ann Arbor, MI 48109, Phone (734) 647-5670
- 2) Taubman Center Infusion Clinic – located downstairs from the GI clinic
1500 West Medical Center Drive, Ann Arbor, MI 48109
- 3) Canton Infusion Clinic located in the Canton Health Center
1051 Canton Center Road, Canton, MI 48187, Phone (734) 844-5400
- 4) Northville Infusion Clinic located in the Northville Health Center
39901 Traditions Drive, Northville, MI 48168 (248) 305-4400.

Please allow 4 hours for your first infusion and then an average of 3 hours for the following ones.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Gut-Specific Anti-Adhesion Therapies (Entyvio® [Vedolizumab])



What are gut-specific anti-adhesion therapies and how do they work?

Anti-adhesion medicines are antibodies that bind to molecules that help white blood cells stick to the blood vessel walls and leave the bloodstream to cause inflammation in the gut. Antibodies are proteins made by our bodies to help get rid of foreign things that can harm us. The integrin alpha 4/beta 7 is a 2-part protein on the surface of white blood cells that home to the gut. It binds to another protein on the blood vessels of the intestines called MAdCAM-1, which is found along the whole digestive tract, from the mouth to the anus. When anti-adhesion antibodies (vedolizumab) are bound to either the integrin alpha 4/beta 7 or MAdCAM-1, this prevents the white blood cells from entering the gut to cause inflammation. Anti-adhesion medicines are included in the category of biologic agents or biologics. They are immunosuppressive medicines. This means that they partially block an action of the immune system, but do not completely it turn off. They are different from other biologics in that they are designed to only cause immunosuppression of the digestive tract. While there are some side effects, most people do not get more infections when they start taking these medicines.



What is alpha 4/beta 7 integrin?

Alpha 4/beta 7 integrin is a protein that is found on the white blood cells that patrol the digestive system and help fight infection. The alpha 4/beta 7 integrin protein helps white blood cells latch onto the inside of a blood vessel and move from the bloodstream into the cells of the gut. Once these white blood cells have moved into the gut they tend to cause inflammation.



What is MAdCAM-1?

MAdCAM-1 is a protein that is found on the lining of the blood vessels of the digestive system. MAdCAM stands for Mucosal vascular Addressin Cell Adhesion Molecule. It is the “address” for the digestive system. The MAdCAM-1 protein helps white blood cells to latch onto the inside of a blood vessel and then move from the bloodstream into the cells of the gut.



What are antibodies and how do they work?

Antibodies are proteins made by the immune system. They are found in the blood and in other body fluids. The job of antibodies is to find, stick to, and work against harmful bacteria, viruses, and proteins. Antibodies make these invaders inactive by attaching to certain places (antigens) on their surface. The anti-adhesion antibodies are made in a lab to do a specific job in the body.



What are the names of anti-adhesion medicines?

There is currently only one anti-adhesion medicine that is FDA-approved for treatment of ulcerative colitis and Crohn’s disease: vedolizumab (**Entyvio**®). It is often called “Vedo” for short.

Entyvio® is used to treat ulcerative colitis and Crohn's disease in adults. It is given in a dose of 300 mg through an intravenous (IV) line. The second and third doses are given 2 weeks and 6 weeks after the first dose. Induction therapy refers to this initial series of three infusions. Maintenance therapy is every 8 weeks.



What are the benefits of taking an anti-adhesion medicine?

If you have flares (uncontrolled inflammation in your intestine) you may need repeated rescue therapy prednisone. Prednisone works very well in the short-term for reducing inflammation and easing your symptoms; however, it has many side effects and is not healthy to take long-term. You are 3 times more likely to require surgery if you take repeated course or use prednisone long-term. If you cannot tolerate or have not gotten a lot better with azathioprine, mercaptopurine, methotrexate or an anti-TNF you may do well with an anti-integrin.

If you do respond, you will have the benefit of not needing to take prednisone for a long period of time. You will also avoid hospitalizations and the complications of inflammation that can lead to surgery. Anti-adhesion therapies can improve your quality of life by controlling your symptoms. About 60% to 70% of patients who take these medicines notice that their symptoms decrease and their test results improve (endoscopy and blood tests measuring inflammation). Up to 40% of patients will be in complete remission (back to normal, with complete control of inflammation) by 6 months. If you do get better or reach remission there is a good chance that you will remain free of symptoms for up to 1 year.



How quickly do anti-adhesion medicines start to work?

It takes time to see the full effect of anti-adhesion therapies: we expect to see the full effect after 12 weeks. Anti-adhesion therapies work best if taken for the long-term. If you are able to tolerate the anti-adhesion medicine, and it is helping to control your disease you should continue taking it for as long as it works. Always talk to your doctor before changing the timing or doses of your medicine or before stopping the medicine.



May I take an anti-adhesion medicine with other medicines used to treat Crohn's disease and ulcerative colitis?

Clinical research studies have not tested whether combining other medicines with anti-adhesion medicines is helpful or harmful. All biologic therapies introduce a foreign protein to your body. At some point, your immune system may recognize this as a foreign protein and try to get rid of the anti-adhesion medicine. Some immunosuppressive medicines, like azathioprine, can prevent your body from making antibodies directed against the anti-adhesion medicines, and can slow the removal of biologic medicines from your body. Future studies will help show whether adding other immunosuppressive medicines to anti-adhesion medicines is helpful.



Is there anything I should avoid while taking an anti-adhesion medicine?

Non-prescription products: Do not take any over-the-counter herbal supplement with echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines, including anti-adhesion medicines.

Prescription medicines: Do not take adalimumab, infliximab, certolizumab, abatacept, anakinra, natalizumab, or rilonacept with anti-adhesion medicines. Other prescription medicines may interact with anti-adhesion medicines. **Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need to have any tests while I am taking an anti-adhesion medicine?

You will be asked if you have any side effects while you are taking an anti-adhesion medicine. There may be increased risk of liver problems during anti-adhesion therapy, so regular liver tests will be performed before each infusion. You may also have regular tests to monitor inflammation in your blood. Because the anti-adhesion medicine blocks the access of gut-homing white blood cells to the gut, it is normal for your white blood cell count to go up while you are on an anti-adhesion medicine.



What are the side effects of anti-adhesion medicines?

Most people who take anti-adhesion medicines don't have any side effects, but they can occur.

Infusion reactions: You may have an intravenous (IV) infusion-related reaction, which is a side effect that occurs within 2 hours of the start of an infusion.

These are allergic reactions that can occur during or within the first six hours after an infusion. While these are rare, allergic symptoms can include rash, itching, swelling of your lips, tongue, throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing). An allergic reaction right away when you start taking an anti-adhesion medicine is rare. True allergic reactions such as shortness of breath, tightness of the chest or throat, wheezing, hives, and anaphylaxis (severe shock) are also rare. You may need to take Benadryl®, Tylenol®, and/or prednisone before your infusion to decrease these reactions. These usually occur during an infusion or within 6 hours afterward. If you have these symptoms, go to the emergency room or call 911.



What are the risks of taking an anti-adhesion medicine?

Resistance: There is a risk that your immune system may make antibodies against the medicine, or start to remove the medicine from your body quickly. If this occurs, you may find that the medicine stops working during the last week or so before the next dose. If this occurs, let your IBD doctor know right away. This may require an adjustment of the dose or time between doses.

Infections: Anti-adhesion medicines can increase your risk for a few specific infections, mostly infections of the digestive tract and tuberculosis. This risk is higher if you take prednisone along

with the anti-adhesion medicine. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

Additional infections occurred during Entyvio therapy (compared to placebo) at a rate of 1 per 100 patients per year in clinical trials. The reported infections included anal abscesses, tuberculosis, salmonella, listeria, giardia, and cytomegalovirus. Anal abscess is more common in Crohn's disease, while the other infections are with organisms that infect the gut, and are more common in unpasteurized foods or untreated water. To reduce infections, it may be important **to avoid unpasteurized dairy products and juices**, and to **drink water that has been treated in a city water system** or to drink bottled water.

Infections BEFORE an infusion - Before receiving Entyvio[®] and during treatment with Entyvio[®], tell your healthcare provider if you think you have an infection or have symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination.

Nasopharyngitis is an inflammation of the nose and throat, producing a runny nose and sore throat. It was the most common infection in clinical trials of vedolizumab.

Abscesses, usually near intestinal strictures or on your bottom, are more common in Crohn's disease, may be more frequent in patients on anti-adhesion medicines, and can produce soreness or swelling, which can burst and drain pus.

Tuberculosis (TB) is a very serious bacterial infection. You are at higher risk for getting TB while taking an anti-adhesion therapy. If you've been exposed to TB in the past it can become active again when you take an anti-adhesion therapy. Before starting to take an anti-adhesion therapy you will have a TB test. Tell your doctor if you have any history of being around someone with TB.

Liver Problems. Liver problems can happen in people who receive Entyvio[®]. Tell your healthcare provider right away if you have any of the following symptoms: tiredness, loss of appetite, pain on the right side of your stomach (abdomen), dark urine, or yellowing of the skin and eyes (jaundice).

You should call your doctor **right away** if you notice any increase in pain, weight loss, or fevers that you cannot explain. If this occurs, blood testing or CT/MRI scanning may be done.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever.**

Theoretical Risk of PML – while the anti-adhesion therapy vedolizumab is designed to be gut-specific and has never been associated with brain infection, the anti-adhesion therapy natalizumab was designed to block inflammation in BOTH the gut and the brain (it binds both

alpha 4/beta 1 and alpha 4/beta 7 integrins) and has led in rare cases to a serious brain infection called PML (progressive multifocal leukoencephalopathy). It is caused by a common virus called JC virus. This is a very serious infection that can cause brain damage or even death.

This led to the design of gut-specific anti-adhesion therapies like vedolizumab. While more than 3000 patients have been treated with vedolizumab (Entyvio®) without a case of PML, the FDA has asked doctors to watch patients carefully for any new neurologic symptoms, like loss of feeling, difficulty speaking, or difficulty with balance while on any anti-adhesion therapy.

Report any new or worsening neurologic symptoms to your doctor right away.

Other risks: The most common side effects of anti-adhesion medicines include: common cold, headache, joint pain, nausea, fever, infections of the nose and throat, tiredness, cough, bronchitis, flu, back pain, rash, itching, sinus infection, throat pain, and pain in extremities.

Pregnancy or Breastfeeding: Tell your doctor if you are pregnant or plan to become pregnant. It is not known if Entyvio® will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving Entyvio®.

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if Entyvio® passes into your breast milk.

University of Michigan Infusion Centers – Vedolizumab infusions are given in our outpatient clinics at the following locations:

1. East Ann Arbor Infusion Clinic located in the East Ann Arbor Health Center
4260 Plymouth Road, Ann Arbor, MI 48109, Phone (734) 647-5670
2. Taubman Center Infusion Clinic – located downstairs from the GI clinic
1500 West Medical Center Drive, Ann Arbor, MI 48109
3. Canton Infusion Clinic located in the Canton Health Center
1051 Canton Center Road, Canton, MI 48187, Phone (734) 844-5400
4. Northville Infusion Clinic located in the Northville Health Center
39901 Traditions Drive, Northville, MI 48168 (248) 305-4400.

Please allow 2–4 hours for your infusions.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Anti-Interleukin 23 Therapies (Stelara® [Ustekinumab])



What are gut-specific anti-interleukin 23 therapies and how do they work?

Anti-interleukin 23 (anti-IL23) medicines are antibodies that bind to molecules that signal to activate white blood cells to cause inflammation in the gut. Antibodies are proteins made by our bodies to bind and help get rid of foreign things that can harm us. Interleukin 23 is a 2-part protein complex that circulates in the blood. It is made of two protein segments, called p40 and p19, with names based on their size. Interleukin 23 shares the p40 subunit with interleukin 12, another activator of the immune system. Stelara® (ustekinumab) binds the p40 subunit, so it blocks both IL12 and IL23. When anti-IL23 antibodies (like ustekinumab) bind to their targets, they prevent the activation of white blood cells and reduce inflammation. Anti-IL23 medicines are included in the category of biologic agents or biologics. They are immunosuppressive medicines. This means that they partially block a particular action of the immune system, but do not completely turn it off. This class of biologic medicines has been proven effective for psoriasis, psoriatic arthritis, and Crohn's disease. While there are some side effects, most people do **not** get more infections when they start taking these medicines.



What are interleukin 23 and interleukin 12?

Interleukins 12 and 23 are protein complexes that help white blood cells communicate between each other (inter for between, leukin for white blood cell). Interleukin 12 and 23 each have two protein chains, and share the p40 subunit. Stelara® (ustekinumab) binds the p40 subunit, so it blocks both IL12 and IL23. Newer medicines in clinical trials bind to the p19 subunit, and only block IL23. Both interleukin 12 and 23 signal to white blood cells to activate them and cause inflammation.



What are antibodies and how do they work?

Antibodies are proteins made by the immune system. They are found in the blood and in other body fluids. The job of antibodies is to find, stick to, and block the action of specific proteins made by bacteria, viruses, and parasites. Antibodies make these invaders inactive by attaching to certain proteins (antigens) on their surface. The anti-IL23 antibodies are designed to bind to IL23 and block its signaling to activate a specific part of the immune system.



What are the names of anti-IL23 medicines?

There is currently only one anti-IL23 medicine that is FDA-approved for treatment Crohn's disease: ustekinumab (Stelara®). Stelara® is used to treat Crohn's disease in adults. The initial dose is given through an intravenous (IV) line, with a dose based on body weight. After this IV loading dose, all maintenance doses are given as injections under the skin (which you can do at home) every 8 weeks. Induction therapy refers to the first IV infusion dose, and maintenance therapy is the under the skin (subcutaneous, or SQ) injection every 8 weeks.



What are the benefits of taking an anti-IL23 medicine?

If you have flares (uncontrolled inflammation in your intestine) you may need repeated rescue therapy with prednisone. Prednisone works very well in the short-term for reducing inflammation and easing your symptoms; however, it has many side effects and is not healthy to

take long-term. You are 3 times more likely to require surgery if you take repeated courses of prednisone or use prednisone long-term. If you cannot tolerate or have not gotten a lot better with azathioprine, mercaptopurine, methotrexate or an anti-TNF, you may do better with an anti-IL23 therapy.

If you do respond, you will have the benefit of not needing to take prednisone for a long period of time. You could also avoid hospitalizations and the complications of inflammation that can lead to surgery. Anti-IL23 therapies can improve your quality of life by controlling your symptoms and preventing complications. About two-thirds of patients who take these medicines notice that their symptoms decrease by 6 weeks of therapy. Up to 53% of patients will be in complete remission (back to normal, with complete control of inflammation) at 1 year. If you do get better or reach remission, there is a good chance that you will remain free of symptoms for up to 1 year.



How quickly do anti-IL23 medicines start to work?

It takes time to see the full effect of anti-IL23 therapies. Some patients will see benefits by 3 weeks, many will see benefits at 6 weeks, and most will see the full effect by 12 weeks. Anti-IL23 therapies work best if taken for the long-term. If you are able to tolerate the anti-IL23 medicine, and it is helping to control your disease, you should continue taking it for as long as it works. Always talk to your doctor before changing the timing or doses of your medicine or before stopping the medicine.



May I take an anti-IL23 medicine with other medicines used to treat Crohn's disease and ulcerative colitis?

Clinical research studies have not tested whether combining other medicines with anti-IL23 medicines is helpful or harmful. All biologic therapies are proteins that are foreign to your body. At some point, your immune system may recognize this as a foreign protein and try to get rid of the anti-IL23 medicine. Some immunosuppressive medicines, like azathioprine, can prevent your body from making antibodies directed against biologic medicines like infliximab (Remicade[®]), and can slow the removal of biologic medicines from your body. It is common to use an immunomodulator like azathioprine for at least the first year of biologic therapy to reduce the risk of forming antibodies against the biologic medicine. Future studies will help show whether adding other immunosuppressive medicines to anti-IL23 medicines is helpful.



Is there anything I should avoid while taking an anti-IL23 medicine?

Non-prescription products: Do not take any over-the-counter herbal supplement with echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines, including anti-IL23 medicines.

Prescription medicines: Do not take adalimumab, infliximab, certolizumab, golimumab, abatacept, anakinra, natalizumab, or rilonacept with anti-IL23 medicines. Other prescription medicines may interact with anti-IL23 medicines. There is some evidence that medicines that are broken down by the CYP450 system in the liver, like Coumadin[®] or cyclosporine could have their levels affected by anti-IL23 medicines. Be sure to have your levels of these medicines

checked regularly after starting an anti-IL23 medicine, as you may need to have your dose adjusted.

Allergy Immunotherapy: It is theoretically possible that taking anti-IL23 therapy may reduce the effectiveness of allergy shots. This has not been tested. It is possible that doses of allergy shots that you have successfully used to induce tolerance in the past could induce an allergic reaction. You should use allergy shots with caution after starting an anti-IL23 medicine.

Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.



Will I need to have any tests while I am taking an anti-IL23 medicine?

You will be asked if you have any side effects while you are taking an anti-IL23 medicine. You may also have regular tests to monitor inflammation in your blood.



What are the side effects of anti-IL23 medicines?

Most people who take anti-IL23 medicines don't have **any** side effects, but they can occur.

Infusion reactions: You may have an intravenous (IV) infusion-related reaction, which is a side effect that occurs within 2 hours of the start of an infusion.

These are allergic reactions that can occur during or within the first six hours after an infusion. While these are rare, allergic symptoms can include rash, itching, swelling of your lips, tongue throat or face, shortness of breath or trouble breathing, wheezing, dizziness, feeling hot, or palpitations (feel like your heart is racing). An allergic reaction that starts right away when you start taking an anti-IL23 medicine is rare. True allergic reactions such as shortness of breath, tightness of the chest or throat, wheezing, hives, and anaphylaxis (severe shock) are also rare. You may need to take Benadryl[®], Tylenol[®], and/or prednisone before your infusion to decrease these reactions. These usually occur during an infusion or within 6 hours afterward. If you have

Injection site reactions: Patients who receive under the skin injections may have local pain, redness, or swelling at the site of injection



What are the risks of taking an anti-IL23 medicine?

Most common risks: The most common side effects occur in 8% or fewer patients on anti-IL23 medicines. None of these occurred in more than 2% more than in patients on a placebo. These include: common cold, headache, fatigue, vomiting, bronchitis, itching, urinary tract infection, sinusitis, vaginal infections, and redness at the skin injection site.

Resistance: There is a risk that your immune system may make antibodies against the medicine, or start to remove the medicine from your body quickly. If this occurs, you may find that the medicine stops working during the last week or so before the next dose. If this occurs, let your IBD doctor know right away. Your IBD doctor may want to check the level of the drug in your blood to see if you still have enough. This may require an adjustment of the dose or time between doses.

Infections: Anti-IL23 medicines can theoretically increase your risk for infections, potentially including tuberculosis, mycobacteria, and salmonella. This risk is higher if you take prednisone along with the anti-IL23 medicine. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than **100.5** degrees call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

Additional infections occurred during Stelara[®] therapy (compared to placebo) at up to 3 per 100 patients per year greater than placebo in clinical trials. The reported infections included nasopharyngitis, vulvovaginal candidiasis, bronchitis, urinary tract infections, and sinusitis. To reduce infections, it could be helpful **to avoid unpasteurized dairy products and juices**, and to **drink water that has been treated in a city water system** or to drink bottled water.

Infections BEFORE an infusion: Before receiving Stelara[®] and during treatment with Stelara[®], tell your healthcare provider if you think you have an infection or have symptoms of an infection such as fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on your body, tiredness, or pain during urination. Viral infections are common, and are not considered a good reason to skip a dose of an anti-IL23 medicine.

Abscesses, usually near intestinal strictures or on your bottom, are more common in Crohn's disease, usually contain a lot of bacteria, and can produce soreness or swelling, which can burst and drain pus. Abscesses or other very serious bacterial infections (pneumonia, cellulitis) are good reasons to talk to your doctor about holding a dose of Stelara[®].

Tuberculosis (TB) is a very serious bacterial infection. You are at higher risk for getting TB while taking an anti-IL23 therapy. If you've been exposed to TB in the past it can become active again when you take an anti-IL23 therapy. Before starting to take an anti-IL23 therapy you will have a TB test. Tell your doctor if you have any history of being around someone with TB.

RPLS (Reversible Posterior Leukoencephalopathy Syndrome) is a rare neurologic condition that is reversible. A single case has been reported in a patient using ustekinumab. RPLS can present with seizures, confusion, headache, and visual disturbances. Notify your doctor immediately if you have these symptoms.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include shingles, **MMR (measles-mumps-rubella)**, **varicella (chickenpox)**, **rotavirus**, **oral polio**, and **yellow fever**.

Pregnancy or Breastfeeding: Tell your doctor if you are **pregnant** or plan to become pregnant. It is not known if anti-IL23 medicines could harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving an anti-IL23 medicine.

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known how much anti-IL23 medicine will pass into your breast milk. It is expected that some of the anti-IL23 biologic, like other antibodies in the body, will pass into breast milk.

University of Michigan Infusion Centers

Anti-IL23 medicine infusions are given in our outpatient clinics at the following locations:

1. East Ann Arbor Infusion Clinic – located in the East Ann Arbor Health Center
4260 Plymouth Road, Ann Arbor, MI 48109, Phone (734) 647-5670
2. Taubman Center Infusion Clinic – located downstairs from the GI clinic 1500 West
Medical Center Drive, Ann Arbor, MI 48109
3. Canton Infusion Clinic – located in the Canton Health Center 1051 Canton Center Road,
Canton, MI 48187, Phone (734) 844-5400
4. Northville Infusion Clinic – located in the Northville Health Center
39901 Traditions Drive, Northville, MI 48168 (248) 305-4400

Please allow 2 hours for your infusions.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

JAK Inhibitor Therapies (Xeljanz [Tofacitinib])

What are the benefits of taking a JAK inhibitor?

JAK inhibitors are oral tablets that are easy to take, and do not require injections or a clinic appointment. JAK inhibitors act quickly to reduce inflammation, with improvement in symptoms in ulcerative colitis often seen after 3 days of therapy. Patients who respond well to JAK inhibitors are likely to be able to continue to have success with these medications long-term, as they are not proteins, and it is very unlikely that your body will form antibodies against the medication.

If you do respond to a JAK inhibitor medication, you will have the benefit of not needing to take prednisone for a long period of time. You could also avoid hospitalizations and the complications of inflammation that can lead to surgery. JAK inhibitor medications can improve your quality of life by controlling your symptoms and preventing complications. About one in 6 patients achieve full remission by 8 weeks of therapy. Up to 46% of patients will be in complete remission (back to normal, with complete control of inflammation, and a completely healed colon) at 1 year.

How quickly do JAK inhibitors start to work?

JAK inhibitors act quickly in ulcerative colitis, with significant changes in symptoms seen after 3 days in many patients. Usually the first noticeable change is a reduction in blood in stool. Most clinical trials with JAK inhibitors measure whether patients reached remission by 8 weeks, though many patients (especially those who started out with very severe inflammation) continue to see improvement beyond 8 weeks.

Dosing for UC Tofacitinib is usually started at 10 mg twice per day in patients with active symptoms, with the potential to reduce the dose to 5 mg twice per day after 8 weeks in patients who respond well. Many patients with active disease will need to stay on the higher dose of 10 mg twice daily. Patients who respond to 10 mg twice daily and taper down to 5 mg twice daily may still intermittently need to increase to 10 mg twice daily to head off a flare.

What are JAK inhibitor therapies and how do they work?

Janus **K**inase (JAK) inhibitor medicines are small molecules that bind to enzymes that normally activate immune cells to cause inflammation in the gut. Small molecules are organic compounds, and in the case of tofacitinib, it is about the same molecular size as sucrose (table sugar). This allows tofacitinib and other JAK inhibitors to be absorbed through the intestine into the bloodstream when taken as an oral tablet. In contrast, antibodies like Remicade or Humira, that are about 500 times larger, cannot be readily absorbed by the oral route, and therefore require injection into the body to be effective.

Janus Kinase is an enzyme inside of cells that phosphorylates other proteins, including those in the STAT family, to send signals to the nucleus to turn on genes that are important in immunity. These include important interleukins (ILs) that signal to activate immune cells, including IL-2, IL-4, IL-6, IL-15 IL-21, and also interferon gamma. Small molecule JAK inhibitors need to be absorbed into the bloodstream and get inside of cells to have their effect on the JAK enzyme. JAK inhibitors are immunosuppressive medicines. This means that they partially block a particular action of the immune system, but do not completely turn it off. This class of medicines has been proven effective for rheumatoid arthritis, ulcerative colitis, psoriasis, and allergic and atopic dermatitis. While there are some specific side effects, most people do **not** generally get more infections when they start taking these medicines. There **is** one specific infection (**shingles**) which develops from reactivation of a previous

infection (chicken pox) that you should be aware of (and vaccinate against) when considering JAK inhibitors.

What are JAK enzymes?

JAK enzymes are important in receiving and amplifying signals to activate immune cells. JAK enzymes are proteins inside the cell that transmit signals from outside the cell received by receptors on the cell membrane. These signals come from other cells, using cytokines. Cells communicate with other nearby cells by sending out cytokines. These cytokines are received by receptors on the surface of the cell, which then activate proteins inside the cell, like JAK enzymes. There are four members of the JAK family, Jak1, Jak2, Jak3, and Tyk2. All of these proteins amplify and transmit signals from cytokines to change the activity of cells. JAK enzymes are important in receiving and amplifying signals to activate immune cells.

What are small molecules and how do they work?

Small molecules are organic chemicals (like aspirin) that are small enough to be absorbed through the intestine into the blood stream, and are small enough to enter cells and block the activity of specific molecules like JAK enzymes. Small molecules often bind to the active site of enzymes, and physically block their normal activity. Small molecules are often less specific than biologic therapies, and may block the activity of several related enzymes (for example, multiple members of the JAK family). Small molecules are so small that they are generally ignored by the immune system. This is different from biologic therapies, which are large proteins that can lead to an immune reaction, and can be recognized as foreign proteins, leading to antibodies that can block the activity of a biologic therapy.

What are the names of JAK inhibitors?

There is currently only one JAK inhibitor medicine that is FDA-approved for the treatment of **ulcerative colitis**: tofacitinib (**Xeljanz®**). **Xeljanz®** (often called tofa) is used to treat ulcerative colitis in adults. There are other JAK inhibitors approved for use in humans, including ruxolitinib (Jakafi) for psoriasis and rheumatoid arthritis, and baricitinib (Olumiant) for rheumatoid arthritis. There is also a JAK inhibitor, oclacitinib (Apoquel), approved veterinary use for allergic and atopic dermatitis in dogs. Several other JAK inhibitors are in development and in clinical trials for a variety of autoimmune conditions.

May I take an JAK inhibitor medicine with other medicines used to treat ulcerative colitis?

Most clinical research studies of JAK inhibitors have not directly tested whether combining other medications with a JAK inhibitor medicine is helpful or harmful. As a general rule, most drug companies avoid combining their drug with other drugs in clinical trials, to avoid any risk of drug interactions. So we don't know much about combinations of other drugs with a JAK inhibitor. Tofacitinib has been tested in combination with methotrexate in rheumatoid arthritis, and did not appear to increase problems or side effects. Many patients in the tofacitinib studies for ulcerative colitis entered the study while on prednisone to control a flare, so we have experience combining tofacitinib with steroids.

We do know that other drug combinations, like Remicade plus Imuran, are better than either drug alone in ulcerative colitis and Crohn's disease. We also know that immunosuppressive drugs like Imuran and methotrexate help protect biologic therapies from formation of blocking antibodies, and that combinations of these drugs with biologics can increase the drug level of biologics, which can be helpful in patients who rapidly clear biologic therapies out of their bloodstream. We think that thiopurine drugs,

like Imuran and 6-MP, act on some of the same pathways as tofacitinib, so we currently think that combining these drugs with tofacitinib would not add much benefit, and might increase the risk of side effects. More experience is needed to determine which combinations of other IBD drugs with Xeljanz are both helpful and safe.

Is there anything I should avoid while taking a JAK inhibitor medicine?

Non-prescription products:

Do not take any over-the-counter herbal supplement with echinacea or cat's claw because these have the ability to diminish the effect of all immunosuppressive medicines, including JAK inhibitors.

Prescription medicines: Other prescription medicines can interact with JAK inhibitors. There is some evidence that medications that are broken down by the CYP450 system in the liver, like *ketoconazole*, *fluconazole*, *tacrolimus*, *cyclosporine*, and *rifampin* could have their levels affected by JAK inhibitors, and vice versa. If possible, you should avoid these medications while on a JAK inhibitor. These medicines can slow the breakdown of a JAK inhibitor, which can increase the level of drug in your blood, and can increase the effects (in a good way), but can also increase the risk of side effects. If avoiding these potentially interacting drugs is not an option, be sure to tell your doctor about taking these medications, as your doctor may want to reduce your dose of the JAK inhibitor drug. Several immunosuppressant tablets, including azathioprine, 6-MP, tacrolimus, and cyclosporine, have not been studied in combination with tofacitinib. There is a theoretical risk of additive immunosuppression, and it is not recommended to combine these medications with a JAK inhibitor.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines, including JAK inhibitors. These include **MMR (measles-mumps-rubella)**, **varicella (chickenpox)**, **rotavirus**, **oral polio**, **yellow fever**, and **the old shingles vaccine (Zostavax)**. The newer shingles vaccine, Shingrix, is not a live vaccine, and is often recommended for patients on JAK inhibitors to reduce your risk of shingles.

Allergy Immunotherapy: It is theoretically possible that taking JAK inhibitor therapy may reduce the effectiveness of allergy shots. This has not been tested. It is possible that doses of allergy shots that you have successfully used to induce tolerance in the past could induce an allergic reaction. You should use allergy shots with caution after starting a JAK inhibitor medication.

Chicken Pox: Tofacitinib (Xeljanz) reduces your immunity to the virus that causes chicken pox. Particularly if you have never had chicken pox, or never developed an immunity to chicken pox, you should avoid anyone with active chicken pox while on Xeljanz.

Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.

Will I need to have any tests while I am taking a JAK inhibitor medicine?

You will be asked if you have any side effects while you are taking a JAK inhibitor. You will also have regular monitoring with laboratory tests. These include blood counts to watch for low lymphocytes, neutrophils, or red blood cells, and liver tests to make sure there is no irritation to the liver. These are

typically tested every 3 months. We will also check to see if the JAK inhibitor medicine raises your cholesterol to a high level. Your doctor may ask you to take a cholesterol-lowering medication (statin) if your cholesterol becomes very high.

What are the side effects of JAK inhibitor medicines?

Most people who take JAK inhibitor medicines don't have **any** side effects, but they can occur.

Common side effects: Those reported in at least 5% of UC patients, at a rate greater than placebo, included infections of the nose and throat, upper respiratory infections, headache, rash, diarrhea, shingles, elevated blood creatine phosphokinase levels, and elevated blood cholesterol levels.

Infections: The risk of serious infections is increased while taking a JAK inhibitor. This risk is particularly increased if you are also taking methotrexate or steroids at the same time. Tuberculosis and shingles are particular risks with Xeljanz. Patients should be tested for latent tuberculosis infection before starting a JAK inhibitor. Other infections can include invasive fungal infections like Cryptococcus and pneumocystis.

You need to have a working thermometer at home to check for a fever whenever you are sick. If your fever is higher than **100.5** degrees F call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue, you need to be seen by your doctor **right away**.

To reduce infections, it could be helpful **to avoid unpasteurized dairy products and juices**, and to **drink water that has been treated in a city water system** or bottled water.

Shingles: Shingles is a recurrence of a previous chicken pox infection. This occurs when the virus hides out in your body in spinal nerve roots. The virus can be reactivated by stress, sunburns, or immune suppression. This starts to occur about 40 years after the original chicken pox infection, so vaccination for shingles is recommended for everyone at age 50. Tofacitinib is associated with an increased rate of shingles, which can start **as early as age 30** in people on immunosuppressive drugs. The Shingrix shingles vaccine (a recombinant vaccine, not a live vaccine) is recommended for patients starting on a JAK inhibitor medication.

Tuberculosis (TB) is a very serious bacterial infection. You are at higher risk for getting TB while taking a JAK inhibitor therapy. If you've been exposed to TB in the past it can become active again when you take a JAK inhibitor therapy. Before starting to take a JAK inhibitor therapy you will have a TB test. Tell your doctor if you have any history of being around someone with TB.

Non-melanoma skin cancers: increased rates of non-melanoma skin cancers were seen in patients taking tofacitinib. Skin protection during sun exposure is very important.

Other cancers: While cancers are rare, cancers have been reported in patients taking tofacitinib (Xeljanz). The most common types of malignancy reported were lung and breast cancer, followed by gastric, colorectal, renal cell, prostate cancer, lymphoma, and malignant melanoma.

Gastrointestinal perforations: perforations have been reported in clinical studies with Xeljanz, although the role of JAK inhibition in these events is not known. In these studies, many patients

with rheumatoid arthritis were also receiving background therapy with Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), which cause damage to the lining of the stomach and intestine.

There was no discernible difference in frequency of gastrointestinal perforation between the placebo and the Xeljanz arms in clinical trials of patients with UC, and many of them were receiving background corticosteroids. It is advised to avoid NSAIDs while taking tofacitinib, and to use with caution in patients with a history of diverticulitis.

Pregnancy, Childbearing, and Breastfeeding

Pregnancy or Breastfeeding: Tell your doctor if you are **pregnant** or plan to become pregnant. It is not known if JAK inhibitor medications could harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving a JAK inhibitor medication. As of 2019, it is not recommended to take Xeljanz during pregnancy. Women who do become pregnant while on a JAK inhibitor are asked to join a registry to study this further to determine whether there are increased risks to the baby.

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known how much JAK inhibitor will pass into your breast milk. It is expected that some of the JAK inhibitor will pass in to breast milk. As of 2019, it is not recommended to take Xeljanz during breastfeeding.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Tysabri®



What is natalizumab (Tysabri®) and how does it work?

Tysabri® is used to treat Crohn's disease and multiple sclerosis. Natalizumab is the generic name for Tysabri®. Tysabri® is an antibody that binds to and blocks the alpha 4 integrin protein found on white blood cells. By blocking this protein, Tysabri® prevents inflammation. It is an immunosuppressive medicine, which means it partially blocks the action of the immune system but does not turn it off completely. While there are some side effects, most people do not get more infections when taking this medicine.



What are antibodies and how do they work?

Antibodies are proteins made by the immune system. They are found in the blood and in other

body fluids. The job of antibodies is to find, stick to, and work against harmful bacteria, viruses, and proteins. Antibodies make these invaders inactive by attaching to certain places (antigens) on their surface.



What is alpha 4 integrin?

Alpha 4 integrin is a protein that is found on white blood cells, which help fight infection. The alpha 4 integrin protein helps white blood cells to latch onto the inside of a blood vessel and then move from the bloodstream into the cells of the gut and the brain. Once these white blood cells have moved into the gut and the brain they tend to cause inflammation.



What are the benefits of taking Tysabri®?

Some people cannot take or do not get better with immunosuppressive medicines commonly used to treat Crohn's disease, like azathioprine (Imuran®) and infliximab (Remicade®). Tysabri® may be effective in controlling the disease symptoms for these people. It has been shown to ease symptoms and bring about a remission in Crohn's disease. The rates for getting better are about the same as an anti-TNF medicine such as Remicade®. Treatment with Tysabri® is one of the last options before surgery. If you get better with Tysabri®, the biggest benefit is that you may not need surgery.



How quickly does Tysabri® work?

Most people see a response within 12 weeks. Tysabri® (300 mg) is given as an IV (intravenous) infusion over 1 hour every 4 weeks. This medicine works best if taken continuously. Increasing the time between treatments may give your body time to make its own antibodies against the medicine, which may reduce or even completely stop it from working. Always talk to your IBD doctor before changing your medicine intervals or if you intend to stop the medicine altogether. If after 12 weeks you cannot taper off prednisone or Entocort® without the return of symptoms, you must stop taking Tysabri®.



May I take Tysabri® with other medicines used to treat Crohn's disease?

You may take an aminosalicylate while taking Tysabri®. Tysabri® should not be used together with other immunosuppressive medicines, such as azathioprine, mercaptopurine, methotrexate, anti-TNFs, or with long-term use of prednisone or Entocort®. Taking Tysabri® with other immunosuppressive medicines for a long time may increase your risk for serious infections, especially herpes infections. It also increases your risk for progressive multifocal leukoencephalopathy (see next page). Your doctor will consider the risks versus the benefits and very well may decide that the benefits of controlling your disease are greater than the risks that come with combining immunosuppressive medicines.



Is there anything I should avoid while taking Tysabri®?

Non-prescription products: Do not take any over-the-counter herbal supplements with echinacea or cat's claw because these reduce the effect of all immunosuppressive medicines, including Tysabri®.

Prescription medicines: Do not take other immunosuppressive medicines or medicines given to treat cancer with Tysabri®, unless directed to do so by your doctor. **Be sure you tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you discuss it with your IBD doctor first.**



Will I need to have any tests while I am taking Tysabri®?

Your doctor will ask you if you have any side effects while taking Tysabri®. You will be monitored for signs of liver damage.



What are the possible side effects?

Some people who take this medicine don't have any side effects.

Allergic reaction: An allergic reaction to Tysabri® is not common. If you are allergic to Tysabri®, the reaction will usually happen right away. The signs are hives, swelling of the face, lips, and tongue, shortness of breath, tightness of the chest and throat, and wheezing. Anaphylactic shock, where you faint or lose consciousness (vascular shutdown), is rare. If you have an allergic reaction to Tysabri®, the infusions must be stopped right away and you must be treated for the reaction. Do not take Tysabri® again.

Infusion reaction: You may experience an infusion-related reaction, which is a side effect that occurs within 2 hours of the start of an infusion. The signs include headaches, being lightheaded, joint and muscle aches, rash, flushing, and nausea. Your doctor may choose to give you Benadryl®, Tylenol®, and/or prednisone before your infusion to decrease these reactions. Subcutaneous (under the skin) injections have the same but fewer reactions than infusions. The

most common is a reaction at the injection site, which may occur in 2% to 5% of cases. This can be reduced by taking Tylenol[®] as well as cooling the area with an ice pack before the injection is given.

Somewhat common side effects: Other possible side effects are depression, fatigue, diarrhea, upper and lower respiratory infections, and urinary tract infections.

Rare side effect: You will be monitored closely for signs and symptoms of liver damage. If you have elevated liver enzymes while taking Tysabri[®], the medicine should be stopped.

 **What are the risks of taking Tysabri[®]?**

Resistance: There is a risk that your immune system will make antibodies against Tysabri[®]. If this occurs, the medicine will be stopped because it becomes less effective.

Infections: Tysabri[®] can increase your risk for infections, especially serious herpes infections. Call your doctor immediately if you are exposed to chicken pox or measles. This risk is higher if you are taking another immunosuppressive medicine while you are taking natalizumab (Tysabri[®]). **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than 100.5 degrees, call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever**.

Progressive multifocal leukoencephalopathy: Tysabri[®] increases the chance of getting a rare viral brain infection called progressive multifocal leukoencephalopathy (PML). This increased risk is about 1 of 7,000 people or 0.01%. This risk increases to about 1/2000 after 18 months of treatment. PML usually only ever occurs in people with weakened immune systems and almost always causes death or severe disability. Symptoms include imbalance, difficulty swallowing, trouble with speech, weakness or paralysis, vision loss, and difficulty thinking. There is no treatment to reverse the brain damage caused by PML. Some treatments can stop it from getting worse and therefore decrease the risk of death. Even though the increased risk for PML is very small while taking Tysabri[®], this infection is very serious. That is why you can only be given this medicine through a special program.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Cyclosporine



What is cyclosporine?

Cyclosporine is an immunosuppressive medicine used to treat severe ulcerative colitis that does not respond to steroids. It is most often used by people who had a kidney, liver, or heart transplant, but it also can be used to treat autoimmune diseases such as rheumatoid arthritis, psoriasis, and IBD. Brand names for cyclosporine include Gengraf[®], Neoral[®], and Sandimmune[®]. Cyclosporine works by slowing down the action of a type of immune cell called a T lymphocyte. It partially blocks the action of the immune system, but it does not completely turn it off. While there are some side effects, most people do not get more infections when they start taking this medicine.



What are the benefits of taking cyclosporine?

If you have a moderate to severe ulcerative colitis flare and do not improve with prednisone you may go into the hospital to be given an intravenous (IV) steroid such as Solu-Medrol[®]. If the IV medicine does not ease your symptoms, it is said that you have steroid-refractory disease. IV cyclosporine in combination with a steroid is often given to those with steroid-refractory ulcerative colitis because it leads to a remission 75% to 80% of the time. If you improve with cyclosporine, you may be able to avoid surgery to remove the colon (colectomy). Cyclosporine is usually given for 3 to 6 months as you make the change to a maintenance immunosuppressive medicine such as azathioprine. Cyclosporine has not been shown to maintain long-term remission. Cyclosporine is not effective in treating Crohn's disease. The only exception is for people with Crohn's disease who have severe fistulizing disease that does not respond to other medicines.



How quickly does cyclosporine work?

You can expect to get better in 5 to 7 days. If cyclosporine does not work, the next step may be surgery to remove the colon.



How should I take cyclosporine?

If you are in the hospital for severe ulcerative colitis, you may start with IV (intravenous) cyclosporine and then move to an oral dose as soon as possible. If you have poor kidney or liver function you may need a smaller dose of cyclosporine.



Can I take cyclosporine with other medicines used to treat Crohn's disease and ulcerative colitis?

You can take 5-aminosalicylic acid (5-ASA) while you are taking cyclosporine. Cyclosporine is taken for about 3 to 6 months as a bridge to another immunosuppressive medicine. It is used with caution when given along with other immunosuppressive medicines, such as azathioprine, mercaptopurine, methotrexate, anti-TNFs, or with long-term use of prednisone or Entocort[®].

because of the increased risk for infection. If your disease is so severe that you need cyclosporine, you will likely need to be taking prednisone along with azathioprine or mercaptopurine as you transition to taking only azathioprine or mercaptopurine. As you make the change, you will take trimethoprim-sulfamethoxazole (Bactrim[®]) to prevent an infection such as *Pneumocystis jirovecii* pneumonia. Taking cyclosporine with other immunosuppressive medicines for a long time may increase your risk for serious infections and also increase your risk for lymphoma. You and your doctor will consider risks and the benefits to choose the best plan for you.



Are there medicines I should avoid while taking cyclosporine?

Non-prescription products: Do not eat grapefruit or drink grapefruit juice while taking cyclosporine because it makes the cyclosporine stronger. Do not take potassium supplements or eat foods, for example bananas, or salt substitutes that are high in potassium. Do not take any over-the-counter herbal products with echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including cyclosporine. Also avoid St. John's wort as it may decrease cyclosporine levels.

Prescription medicines: There are many medicines that interact with cyclosporine. Ask your doctor or pharmacist if your other medicines are safe to take with cyclosporine. Common medicines to avoid while taking cyclosporine include ACE inhibitors, calcium channel blockers, carbamazepine, colchicine, fluconazole and other anti-fungals. Some other medicines to avoid while taking cyclosporine include aliskiren, amiodarone, barbiturates, cardiac glycosides, carvedilol, dabigatran etexilate, doxorubicin, ezetimibe, fentanyl, griseofulvin, HMG CoA reductase inhibitors, methotrexate, mycophenolate, natalizumab, NSAIDs, phenytoin, protease inhibitors, rifamycin derivatives, sirolimus/somatostatin analogues, tacrolimus, and temsirolimus. Do not stop taking the medicines prescribed for you unless you are advised to do so by your doctor. **Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, and herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need to have any tests while I am taking cyclosporine?

You will have routine blood tests to check your electrolytes, such as potassium and magnesium, and your liver and kidney function, which may be affected by the medicine. The level of cyclosporine in your blood will be measured, as well as the levels of inflammatory markers and lipids. Your blood pressure will also be checked at each visit. It is common to have your blood test done every week for 2 weeks then every 2 weeks for a month and monthly thereafter. Your dose of medicine may change based on your blood tests. A change in your dose may mean a change in the schedule of blood tests. Your doctor will keep a record of the results of your blood tests. Be sure to tell your doctor about any other medicines you are taking because they may affect the level of cyclosporine in your body.



What are the side effects of cyclosporine?

Allergic reaction: You are unlikely to have an allergic reaction to cyclosporine when you first start taking it. True allergic reactions such as hives, swelling of the face, lips, and tongue, shortness of breath, tightness of the chest and throat, and wheezing are rare. Anaphylactic shock, where you faint or lose consciousness (vascular shutdown), is rare. If you have an allergic reaction, go to the emergency room or call 911.

Common side effects include headache, tremor, numbness, tingling, seizures, increased hair growth, kidney problems, high blood pressure, swelling of the feet or ankles or general swelling, leg cramps, upper respiratory infection, other infections, nausea, increased triglycerides, diarrhea, abdominal discomfort, and stomach upset.

Uncommon side effects include increased blood potassium, decreased blood magnesium, enlargement of gum tissue, pancreatitis (inflammation of the pancreas), and change in liver function.



What are the risks of taking cyclosporine?

Kidney: Poor kidney function, including kidney damage, may occur when cyclosporine is used at high doses. Your kidney function will be checked with a blood test.

Liver: Levels of liver enzymes and bilirubin may rise when cyclosporine is used at high doses. They usually go back to normal when the dose of medicine is reduced.

Hypertension: Your blood pressure will be closely monitored while you are taking cyclosporine.

Seizures: If you have low lipid (blood fat) levels you may be at risk for seizures. Your lipid level will be checked before starting you on cyclosporine.

Lymphoma: Because cyclosporine is an immunosuppressive medicine there is a small risk for getting lymphoma, which is a type of cancer. It is not clear if this risk is due to the medicine or to the IBD. You will be monitored closely while you are taking cyclosporine. Tell your doctor right away if you notice any increase in pain, weight loss, or ongoing fevers you cannot explain. If any of these occur, blood tests or a CT scan may be needed. Be sure to tell your doctor if you have cancer now or if you had cancer in the past.

Infections: There is an increased risk for infection, such as *Pneumocystis carinii* pneumonia. This risk is higher if you are taking another immunosuppressive medicine while you are taking cyclosporine. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than 100.5 degrees, call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever**.

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Tacrolimus



What is tacrolimus and how does it work?

Tacrolimus (Prograf[®]) is an immunosuppressive medicine, used to treat severe ulcerative colitis that does not respond to corticosteroids and fistulizing Crohn's disease that does not respond to the standard medicines. Tacrolimus is most often used by people who have had a kidney, liver, or heart transplant, but it also can be used to treat autoimmune diseases such as severe rheumatoid arthritis and psoriasis. Tacrolimus works by slowing down the action of a type of immune cell called a T lymphocyte. It partially blocks the action of the immune system, but it does not completely turn it off. While there are some side effects, most people do not get more infections when they start taking this medicine.



What are the benefits of taking tacrolimus?

If you have a moderate to severe ulcerative colitis flare and do not improve with prednisone you may go into the hospital to be given intravenous (IV) corticosteroids such as Solu-Medrol[®]. If the IV medicines do not ease your symptoms, it is said that you have steroid-refractory disease. Oral tacrolimus in combination with steroids is sometimes given to those with steroid-refractory ulcerative colitis because it may lead to a remission. Oral tacrolimus at 0.2 mg/kg daily has also been shown to improve fistulizing Crohn's disease.



How quickly does tacrolimus work?

If you take your medicine regularly you should start to get better in 2 to 4 weeks. Always talk to your doctor before decreasing your dose or stopping the medicine.



How should I take tacrolimus?

It is better to take tacrolimus 30 minutes before or 30 minutes after a meal. Do not take it 2 hours before or after taking an antacid. Your dose is based on your body weight. If your kidney or liver function is impaired, you will take a smaller dose. Do not change your dose or stop taking this medicine without talking to your doctor. Drink plenty of fluids (2–3 quarts per day) while you are taking tacrolimus unless you have been told to limit fluids.



Can I take tacrolimus with other medicines used to treat Crohn's disease and ulcerative colitis?

It is safe to take a 5-ASA medicine while you are taking tacrolimus. Tacrolimus is usually not given with other immunosuppressive medicines such as azathioprine, mercaptopurine, methotrexate, anti-TNFs, or with long-term use of prednisone or Entocort[®]. Taking tacrolimus with other immunosuppressive medicines for a long time may increase your risk for getting a serious infection and also increases your risk for lymphoma. You and your doctor will consider the risks and the benefits to choose the best plan for you.



Are there medicines I should avoid while taking tacrolimus?

Non-prescription products: Do not eat grapefruit or drink grapefruit juice or alcohol while taking tacrolimus. Do not take any over-the-counter herbal products with echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including tacrolimus. Also avoid St. John's wort as it may decrease tacrolimus levels.

Prescription medicine: Many prescription medicines interact with tacrolimus. Ask your doctor or pharmacist if your other medicines are safe to take with tacrolimus. Common medicines to avoid while taking tacrolimus include antacids, Prozac® (and other serotonin reuptake inhibitor antidepressants), fluconazole (and other anti-fungals), and triamterene (and other potassium-sparing diuretics). Other medicines to avoid while taking tacrolimus include cyclosporine, dabigatran etexilate, natalizumab, protease inhibitors, rifamycin derivatives, sirolimus, or temsirolimus. Tacrolimus is metabolized (broken down) by the cytochrome P450 enzyme system, so any medicine that interferes with this system will change the effects of tacrolimus in your body. **There are several of these kinds of medicines so be sure to tell your doctor about every prescription and over-the-counter medicine you are taking. This includes vitamins and herbal products as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you discuss it with your IBD doctor first.**



Will I need to have any tests while I am taking tacrolimus?

You will have routine blood tests to check your electrolytes, such as potassium and magnesium, and your liver and kidney function, which may be affected by tacrolimus. The level of tacrolimus in your blood will be measured, as well as the levels of inflammatory markers and lipids. Your blood pressure will also be checked at each visit. It is common to have your blood test done 3 times a week at first and then less often as time goes by. Your blood pressure and blood glucose level will also be checked at the same time. Your dose of medicine may change based on your blood tests. A change in your dose may mean a change in the schedule of blood tests. Your doctor will keep a record of the results of your blood tests. Be sure to tell your doctor about any other medicines you are taking because they may affect the level of tacrolimus in your body.



What are the side effects of tacrolimus?

Allergic reaction: You are unlikely to have an allergic reaction to tacrolimus when you first start taking it. True allergic reactions such as hives, swelling of the face, lips, and tongue, shortness of breath, tightness of the chest and throat, and wheezing are rare. Anaphylactic shock, where you faint or lose consciousness (vascular shutdown), is rare. If you have an allergic reaction, go to the emergency room or call 911.

Common side effects include headache, dizziness, tremor, numbness, tingling, trouble sleeping (insomnia), weakness, abdominal pain, constipation, diarrhea, stomach upset, nausea, vomiting, anemia, elevated or low white blood cell count, low platelets, and joint pain.

Uncommon side effects include chest pain, hypertension, increased creatinine level in the blood, leg cramps, diabetes, elevated blood sugar, elevated or decreased blood potassium, decreased blood magnesium or phosphate, elevated lipids, fluid in the abdomen, back pain, abnormal kidney function, decreased urine output, urinary tract infection, bronchitis, difficulty breathing, fluid between the lining of the lungs, and cytomegalovirus (CMV) infection.



What are the risks of taking tacrolimus?

Kidney: Poor kidney function, including kidney damage, may occur when tacrolimus is used at high doses. Your kidney function will be checked with a blood test.

Liver: Levels of liver enzymes and bilirubin may rise when tacrolimus is used at high doses. They usually go back to normal when the dose of medicine is reduced.

Hypertension: Your blood pressure will be monitored closely while you are taking cyclosporine.

Seizures: If you have low lipid (blood fat) levels you may be at risk for seizures.

Lymphoma: Because tacrolimus is an immunosuppressive medicine there is a small risk for getting lymphoma, which is a type of cancer. It is not clear if this risk is due to the medicine or to the IBD. You will be monitored closely while you are taking tacrolimus. Tell your doctor right away if you notice any increase in pain, weight loss, or ongoing fevers you cannot explain. If any of these occur, blood tests or a CT scan may be needed. Be sure to tell your doctor if you have cancer now or if you had cancer in the past.

Infections: There is an increased risk for infection, such as *Pneumocystis carinii* pneumonia. This risk is higher if you are taking another immunosuppressive medicine while you are taking tacrolimus. **You need to have a working thermometer at home to check for a fever whenever you are sick.** If your fever is higher than 100.5 degrees, call your doctor's office **RIGHT AWAY**. If you have a fever, cough, malaise (general sick feeling), trouble breathing, or if you notice new or increasing fatigue you need to be seen by your doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include: **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever.**

This information is not meant to cover all uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have questions about the medicines you are taking, please talk to your doctor, nurse, or pharmacist.

Mycophenolate



What is mycophenolate and how does it work?

Mycophenolate is an immunosuppressive medicine. Brand names include CellCept[®] and Myfortic[®]. It is used to treat ulcerative colitis that does not respond to standard medicines. It is most often used by people who have had a kidney, liver, or heart transplant. Mycophenolate is used to treat autoimmune diseases such as severe atopic dermatitis, myasthenia gravis, and Wegener's granulomatosis. Mycophenolate blocks the increase in the numbers of white blood cells called T cells and B cells, in order to reduce inflammation. As mentioned, mycophenolate is an immunosuppressive medicine, which means it partially blocks the action of the immune system, but it does not completely turn it off. While there are some side effects, most people do not get more infections when they start taking this medicine.



What are the benefits of taking mycophenolate?

Some people who cannot tolerate or do not improve with the immunosuppressive medicines commonly used to treat ulcerative colitis, such as azathioprine (Imuran[®]), methotrexate, or infliximab (Remicade[®]). It is said that these people have refractory disease. Mycophenolate may help those who do not improve when they take IV (intravenous) corticosteroids such as prednisone; however, this has not been shown in a controlled clinical study. If you improve while taking mycophenolate, you will have the benefit of limiting the time you need to take to corticosteroids like prednisone. In addition, you may be able to avoid the complications of untreated inflammation that can lead to surgery.



How quickly does mycophenolate work?

It takes 4 to 12 weeks for mycophenolate to work (if it does work).



How should I take mycophenolate?

Mycophenolate can be hazardous, so you must handle it carefully. It has been shown to cause birth defects in rats and rabbits. Do not crush tablets or open or crush capsules. Do not inhale the powder in the capsules or the powder used to make a solution. Do not let the powder touch your skin or the moist lining of your mouth, nose, and eyes. If it does touch your skin, wash well with soap and water. If it goes in your eyes, rinse your eyes with plain water.

Take mycophenolate on an empty stomach, 1 hour before or 2 hours after meals. Do not take it 1 hour before or 2 hours after taking an antacid or a cholestyramine medicine (for example, Questran[®]). If you take the delayed release tablets, these should not be crushed, cut, or chewed. At the beginning, you may be given 1 g twice daily in an IV (intravenous) infusion over at least 2 hours. If you are taking oral mycophenolate, do not change the dose or stop taking this medicine without talking to your doctor. Drink plenty of fluid (2 to 3 quarts every day as long as you are taking this medicine, unless you have been told to limit fluids).



Can I take mycophenolate with other medicines used to treat Crohn's disease and ulcerative colitis?

You can take a 5-ASA medicine while you are taking mycophenolate. Mycophenolate should not be taken with other immunosuppressive medicines such as azathioprine, mercaptopurine, methotrexate, anti-TNFs, or with the long-term use of prednisone or Entocort®. Taking mycophenolate with other immunosuppressive medicines for a long time may increase the risk for serious infections. The risk for lymphoma also increases. You and your doctor will consider the risks and the benefits to choose the best plan for you



Are there medicines I should avoid while taking mycophenolate?

Non-prescription products: Do not take any over-the-counter herbal products with echinacea or cat's claw because these can reduce the effect of all immunosuppressive medicines, including mycophenolate.

Prescription medicines: Common medicines to avoid while taking mycophenolate include antacids and birth control pills (oral contraceptives). Also, do not take azathioprine, cholestyramine resin, cyclosporine, magnesium salts, metronidazole, natalizumab, norfloxacin, probenecid, rifamycin derivatives, or sevelamer. **Be sure to tell your doctor about all the prescription and over-the-counter medicines you are taking. This includes vitamins, minerals, herbal products, as well as medicines prescribed by other doctors. Do not start a new medicine prescribed by a different doctor without telling your IBD doctor. Also, do not stop taking the medicines prescribed for you unless you talk to your IBD doctor first.**



Will I need to have any tests while I am taking mycophenolate?

If you have diabetes you need to check your blood glucose levels often with your home glucose monitor. You will also be checked routinely for signs of infection. You may have your blood tested if an infection is suspected. We often check blood counts regularly as mycophenolate can reduce the white blood cell count.



What are the side effects of mycophenolate?

Allergic reaction: You are unlikely to have an allergic reaction to mycophenolate when you first start taking it. True allergic reactions such as hives, swelling of the face, lips, and tongue, shortness of breath, tightness of the chest and throat, and wheezing are rare. Anaphylactic shock, where you faint or lose consciousness (vascular shutdown), is rare. If you have an allergic reaction, go to the emergency room or call 911.

Common side effects: High blood pressure (hypertension), swelling in the legs, headache, trouble sleeping (insomnia), tremor, fever, dizziness, weakness, pricking or tingling of the skin, anxiety, rash, high blood glucose, high cholesterol, decreased blood potassium, calcium and magnesium, high blood potassium, abdominal pain, nausea, diarrhea, constipation, vomiting, loss of appetite, stomach upset, urinary tract infection, decreased kidney function, blood urea nitrogen (BUN) level increased, creatinine increased, leukopenia, leukocytosis, hypochromic

anemia, thrombocytopenia, abnormal liver function tests, ascites, back pain, dyspnea, respiratory tract infection, cough, lung disorder, respiratory infection, *Candida* (yeast) infection, herpes simplex infection.



What are the risks of taking mycophenolate?

Infections: The risk for infection increases. This risk is higher if you are taking another immunosuppressive medicine while you are taking mycophenolate. **You should have a working thermometer at home to measure your temperature when you are sick.** Every time you feel unwell, you must check your temperature. If you have a fever higher than 100.5 degrees, call your doctor's office **RIGHT AWAY**. Patients with fever, cough, malaise (general sick feeling), difficulty breathing, or new or increasing fatigue need to see their doctor **right away**.

NO LIVE VACCINES: You should **NEVER** be given a live vaccine while you are taking any immunosuppressive medicines. These include **MMR (measles-mumps-rubella), varicella (chickenpox), rotavirus, oral polio, and yellow fever.**

Neutropenia: Neutropenia is a decrease in the numbers of the white blood cells called neutrophils. White blood cells are needed to fight infection. If severe neutropenia occurs, you will stop taking your mycophenolate.

Lymphoma: Because mycophenolate is an immunosuppressive medicine, there is a small risk for getting lymphoma, which is a type of cancer. You will be monitored closely while you are taking tacrolimus. Tell your doctor right away if you notice any increase in pain, weight loss, or ongoing fevers you cannot explain. If any of these occur, you may have a blood tests or a CT scan. Be sure to tell your doctor if you have cancer now or if you had cancer in the past.

Skin Cancer: Mycophenolate may also increase the risk for certain types of skin cancer. The amount of risk is related to dose of mycophenolate and how long you take it. The risk is higher if you take another immunosuppressive medicine along with mycophenolate. Use sun block when you spend time outside and do not use tanning beds. You may also need to have yearly skin exams by a dermatologist.

Progressive multifocal leukoencephalopathy: The chance of getting a rare viral brain infection called progressive multifocal leukoencephalopathy (PML) is increased when taking mycophenolate. PML only occurs in people who have weak immune systems and almost always causes death or severe disability. Symptoms include poor balance, trouble swallowing, trouble with speech, weakness or paralysis, vision loss, and trouble thinking. There is no treatment to reverse the brain damage caused by PML. Some treatments can stop it from getting worse and decrease the risk of death.

Peptic ulcer disease: Patients with active peptic ulcer disease may be at higher risk for bleeding and perforation. People with peptic ulcer disease who take mycophenolate are monitored very closely.

Hypoxanthine-guanine phosphoribosyltransferase deficiency: People with the rare defect of a lack of hypoxanthine-guanine phosphoribosyltransferase (such as Lesch-Nyhan or Kelley-Seegmiller syndrome) should not take mycophenolate.



Becoming pregnant while taking mycophenolate

NO WAY!! Mycophenolate has been shown to cause birth defects. Women who are of childbearing age should have a negative pregnancy test 1 week before starting to take mycophenolate. Two reliable forms of birth control should be used 4 weeks before, during, and for 6 weeks after treatment with mycophenolate. Two forms of birth control must be used because birth control pills may be less effective when taking mycophenolate. You may be asked to sign a contract saying you will use reliable birth control. You should **ABSOLUTELY NOT** take mycophenolate during pregnancy. If you think you are pregnant, stop taking mycophenolate **right away** and call your doctor to arrange a pregnancy test. Breast-feeding is not recommended while taking mycophenolate or for 6 weeks after you stopped taking it.

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Surgery for Inflammatory Bowel Disease

Ulcerative Colitis

Possible reasons for surgery:

- Symptoms do not get better or you are unable to tolerate medicine
- Not able to maintain your nutrition and weight
- Very poor quality of life
- Dysplasia (pre-cancer)

People with complications of severe ulcerative colitis such as perforation (hole in lining of intestine) or severe bleeding need surgery right away. People who have ulcerative colitis for a long time, have a higher risk for colon cancer. Pre-cancerous changes or colon cancer are other reasons for surgery. Because ulcerative colitis only affects the colon, once the colon is removed, symptoms are much better. The surgery can be done either openly (a large cut) or laparoscopically (a few small cuts). Sometimes, two or three separate operations are needed. About 30% of Ulcerative colitis patients will need surgery in their lifetime.

Common types of surgeries for ulcerative colitis:

Proctocolectomy – This type of surgery removes the colon and the rectum. It is sometimes called a colectomy. A permanent ileostomy may need to be done. Other times an ileal pouch–anal anastomosis (connection) is done.

Ileostomy – This is done after a proctocolectomy. It involves bringing the end of the small intestine (ileum) through a hole (stoma) in the wall of the abdomen. This allows the intestinal contents (waste) to drain into an ostomy bag worn outside the body.

Ileal pouch–anal anastomosis – This is also called a restorative proctocolectomy. This allows a person to pass stool through the anus. It is done by removing the colon and rectum, then turning the ileum into a pouch and connecting it to the anus. An ostomy bag is worn for about 12 weeks so that the internal pouch can heal.

Subtotal colectomy – This involves removing only part of the colon. The rectum or the rectum and part of the sigmoid colon (last 10–20 cm) is not removed.

Crohn's Disease

Possible reasons for surgery:

- Symptoms do not get better or unable to tolerate medicine
- Complications, including strictures (narrowed areas of intestine), perforations, or bleeding
- Abscesses or fistulas that do not heal

Surgery cannot cure Crohn's disease, but it may greatly improve symptoms and quality of life. However, the disease often reappears in another area of the intestines. This is mostly likely to

occur where the surgery was done. About two-thirds to three-quarters of people with Crohn's disease will need surgery at some point.

Common types of surgeries for Crohn's disease:

Fistula – The most common surgery to repair a fistula is a resection (removal of affected part) and anastomosis (reconnecting healthy parts).

Abscesses – An abscess may be treated in one of two ways: It may be drained by inserting a needle in the skin, or the abscess may be removed.

Resection – This is the most common type of surgery done for Crohn's disease. The affected part of the intestine is removed and the two healthy ends of the intestine are attached. Putting the two ends together is called an anastomosis.

Strictureplasty – This is done to widen a stricture (narrowing) in the small intestine. A cut is made along the narrowed area, the two ends of the cut are pushed together, and then the intestine is sewn together.

Colectomy – This involves removing the entire colon. Sometimes a permanent ileostomy is done. Other times an ileal pouch–anal anastomosis (connection) is performed.

Proctocolectomy – This involves the removal of both the colon and the rectum. Sometimes a permanent ileostomy is done. Other times an ileal pouch–anal anastomosis (connection) is performed.

Ileostomy – This is done most commonly after a proctocolectomy. It involves bringing the end of the small intestine (ileum) through a hole (stoma) in the wall of the abdomen. This allows the intestinal contents (waste) to drain into an ostomy bag worn outside the body.

Some information and tips:

- Up to 70% of people with IBD will need surgery at some point.
- Talk with your doctor or a dietitian about your diet before and after surgery.
- Ask questions and learn as much as you can about your surgery.
- If you understand what is going to happen, it will help you to feel calmer, less afraid, and you won't have any surprises.

Fistula Therapy: Setons and Collagen Plugs

Sometimes setons (silk string or rubber bands) and collagen plugs are used to treat perianal fistulas. Setons help a fistula continue to drain so that it does not form an abscess. Setons also help scar tissue to form around the fistula. The scar tissue can then be removed by surgery.

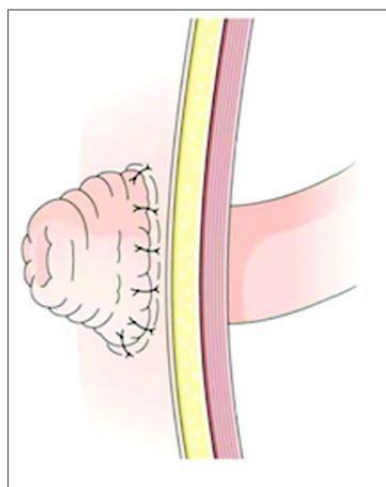
Collagen plugs are made of collagen protein and may be used to seal a fistula tract. If you have any questions about these options, ask your doctor or nurse.

Ileostomy versus Ileal Pouch–Anal Anastomosis

People who have an ileostomy have fewer problems after surgery and it seems to last longer than an ileal pouch–anal anastomosis. An ileal pouch–anal anastomosis looks better but more surgery may be needed in the future.

Standard Ileostomy

This method has been used for a long time. It works very well even today when new methods are offered. It involves removing the entire colon and the rectum. The anus is closed. The small intestine is brought out to the skin and the inner lining is pulled over the tube of the bowel. An ostomy bag is worn outside the body. It is usually a single surgery.



Positives of an ileostomy:

1. Single operation – all inflamed tissue is removed.
2. No risk for colon cancer.
3. Less time to return to usual activity

Negatives of an ileostomy:

The major concerns of most patients are how it will look and affect their lives.

1. Can it be seen?
2. Can I have a bath? Can I go swimming?
3. Will the bag fall off?
4. What about gas? Will it smell?
5. What about diet?

Your IBD doctor, your surgeon, and your nurse will talk to you about your concerns and answer any questions you have. The UoAA (Ostomy Association) website is also helpful.

The need for repeat surgery

Over time, 25% to 50% of people find that the ileostomy needs to be put in a different place (“re-siting”). The longer you live with an ileostomy, the more likely you are to need surgery. Hernias around the stoma and retraction (scarring after surgery pulls the tube back in) require repeat surgery.

We will answer all of your questions before and after surgery. We want to do all that we can to make sure that both your quality of life and health are good after surgery.

Ileal Pouch–Anal Anastomosis

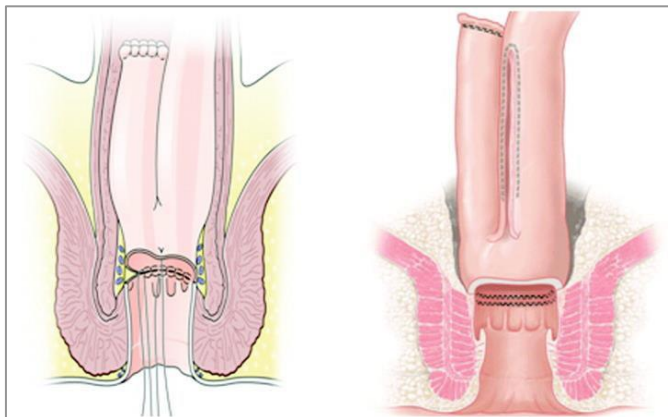
The entire colon is removed and a small cuff of rectum is left. The small intestine is then made to create a new rectum. This is called a J-pouch and it is attached to the rectal cuff. This surgery usually requires that an ostomy bag be worn for a short time so that the internal pouch can heal. A second surgery is needed to “take down” the temporary ileostomy and attach the J-pouch to the rectal cuff. A third operation may be needed as well.

Positives of ileal pouch–anal anastomosis:

1. Lifestyle – no bag, go to bathroom in the usual way
2. Less than 10% need more surgery in the future.

Negatives of ileal pouch–anal anastomosis:

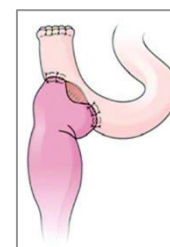
1. Usual bowel pattern is 6 to 10 bowel movements per day even 1 year after surgery.
2. Fecal incontinence (unexpected leakage of stool or the inability to control bowel movements) does occur at first, but improves with time.
3. Inflammation of the J-pouch occurs in 40% to 60% of patients. Medicine is needed to treat an inflamed pouch.
4. 10% of patients need the same medicines that they were taking before surgery.
5. Risk for cancer is much lower, but the rectal cuff still needs to be checked for cancer regularly.
6. Time to return to full activities may take up to 1 year.



Gender-related issues

- The ability to become pregnant is lower with this surgery. It may be as low as 38% in the first years after surgery. If this is a concern, talk to your doctor before surgery.
- Retrograde ejaculation (semen goes backward, not forward) is rare but can cause infertility in men.

Ileal pouch–rectal anastomosis is an alternative to ileal pouch–anal anastomosis.



Therapeutic Studies in Clinical Research

Why should I join a clinical study?

Many people with IBD join clinical studies, and there are many good reasons to do so. These include:

1. Wanting to find a therapy that works better than current options

- Taking part in clinical studies gives you a chance to try new treatments that are not FDA approved or on the market.
- Basic research is finding new methods and medicines that may control IBD. We won't know if these work well until people with IBD try them.

2. To be monitored more closely

- People who take part in clinical studies are checked more closely than in usual clinical care. This is due to safety rules and the need to keep track of things for the FDA.
- People in clinical studies (mainly cancer studies) do better than people who are not in clinical studies. This may be due to the closer monitoring.

3. Wanting to contribute to progress in IBD research

There are slightly over a million people with IBD in the United States. This is not a huge number. So, in order to make progress in IBD research, people need to join clinical studies. Unlike more common diseases like diabetes, progress in IBD needs many of the people with IBD to join in clinical studies.

Why do people not want to join a clinical study?

1. Worried they won't get the best treatment on the market

Federal rules require you to have the best treatment there is today PLUS any new therapy. You will not be refused any treatment than is known to work.

2. Worried about getting placebo

To truly test if a drug works, it must be compared to a placebo. Some people will be assigned by chance (a randomized study) to get a placebo, along with their usual medicines. Some studies allow people to cross over to the medicine being tested if they don't get better. Other studies (open-label) allow people to receive the test medicine after the study ends.

3. Worried about committing to a study and not being able to get out

You can change your mind and stop being part of a study at any time. This is based on federal rules for research. If you decide to stop taking part in a study, your care will not be affected in any way.

Think about it. The only way to know if new medicines work is to give them a try.

Diet and Inflammatory Bowel Disease



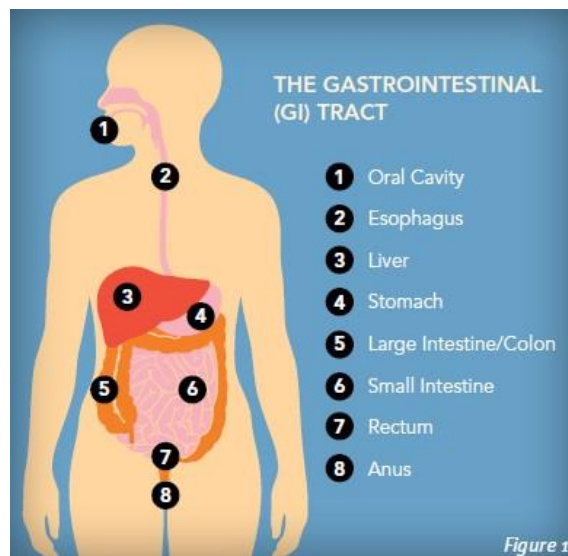
Did my diet cause IBD?

No. IBD seems to be caused by a mix of genes and things that damage the lining of the intestine. Together, these cause the immune system to be exposed to the bacteria in the intestine more than usual. Inflammation in the intestine of a healthy person lasts for a short time, and then goes away. In people with IBD, the inflammation does not go away, and the intestine stays inflamed. IBD is more common in Western countries, such as the United States. No one diet or food has ever been linked to the cause of IBD, and there is no proof that anything in a person's past diet caused his IBD.



How is food digested?

Digestion is the process of breaking down food into smaller and smaller pieces so it can be used by the body or eliminated as waste. Here is how it happens. When the food you eat goes into your stomach, it is mixed with acid and enzymes that break it down into small pieces. Just past the stomach, in the small intestine, water is added as well as enzymes and bile from the pancreas and liver, which break these pieces down even more. The nutrients your body needs are absorbed through the lining of the small intestine into the blood vessels, where they travel through the bloodstream to the cells throughout the body. What cannot be digested in the small intestine (mostly watery food residue) moves into the large intestine, which is also called the colon. The colon absorbs and recycles much of the water. The food residue is now solid (stool) and is passed from the large intestine as a bowel movement through the anus.



When the small intestine is inflamed in Crohn's disease, it is less able to fully digest and absorb the nutrients from food. This can lead to malnutrition because the nutrients pass through to the colon, causing watery diarrhea. When the large intestine is also inflamed, the diarrhea may become more severe.

In ulcerative colitis and Crohn's colitis (Crohn's disease affecting only the colon), the colon is inflamed and the small intestine continues to work normally. However, because the inflamed colon does not recycle water as it should, the diarrhea can be severe. If the colon is very inflamed, proteins can leak out from the bloodstream into the stool. When the protein levels are very low in the bloodstream, fluid often leaks out into the soft tissues, causing swelling. The swelling often starts in the lower legs and ankles.



Is IBD caused by allergies to foods?

No. Although some people with IBD have allergies to certain foods, neither Crohn's disease nor ulcerative colitis is caused by food allergy.



Do certain foods make the inflammation worse?

No. Although certain foods can make the symptoms worse, there is no proof that inflammation of the intestine is directly affected by food. However, food that has gone bad can lead to food poisoning or infection.



Can IBD be cured with a special diet?

No. There is no proof that any diet will truly stop or prevent the inflammation of IBD. The goal is to try to eat a well-balanced, healthy diet. Healthy eating habits are good for everyone, but they are even more helpful for people with IBD. A healthy diet will give you the nutrients you need which can help to heal the inflammation.

There are diets that have been shown to reduce the symptoms of IBD. These diets reduce the amount of different types of sugars in the diet that cause bacteria to create gas in the intestine, which can lead to pain, bloating, and cramping. The best proven diet is the FODMAP™ diet. This diet was shown to reduce bloating and cramping in a well-done study among people with Crohn's disease. The FODMAP™ diet does not reduce inflammation, but does ease the symptoms. So, the bottom line is that it may be worthwhile to try the FODMAP diet to improve symptoms, but be sure to keep taking your other medicines because no diet has been proven to heal inflammation.

There are many other diets that are heavily marketed as a treatment or cure for IBD. There is no solid proof to support these claims. Some diets limit fermentable sugars, like the FODMAP™ diet, and may have similar benefits. Also, tell your health care team if you try a diet. They can help you to be sure that you are getting the nutrients your body needs.

An all-liquid diet of pre-digested nutrients, called an elemental or polymeric diet, has been shown to reduce inflammation in the intestine. It is usually given overnight through a tube that runs through the nose to the stomach. This approach eliminates eating all food by mouth for 8 to 12 weeks. It can improve symptoms and reduce inflammation, but it is very hard for most people to do.

What are FODMAPs and why should I avoid them?

FODMAPs are sugars (carbohydrates) in the foods that we eat that are poorly absorbed by the gut. The intestinal bacteria in the gut can react to these foods and cause abdominal pain, gas, bloating, diarrhea and/or constipation. When foods rich in FODMAPs are removed from the diet of patients with Irritable Bowel Syndrome (IBS), **75% of patients will see a reduction in, or in some cases, a resolution of their GI symptoms.** Reducing intake of high FODMAP foods may also help decrease GI symptoms for patients with Crohn's or Ulcerative Colitis (Inflammatory Bowel Diseases or IBD). IBD patients who try the low FODMAP diet should not be having a flare.

FODMAP is an acronym for:

Fermentable (produces gas in the intestines)

Oligosaccharides (fructans and galactans/GOS)

Disaccharides (lactose)

Monosaccharides (excess fructose)

And

Polyols (sugar alcohols like sorbitol, maltitol, mannitol, xylitol and isomalt)

What foods should I avoid that contain FODMAPs?

The following list is an example of **some** of the foods high in FODMAPs. This list is just an example and **is not complete.**

- Fructans and galactans/GOS: wheat, rye, barley, onion, garlic, inulin/chicory root, most legumes, artichoke, soy milk, rice milk, coconut milk
- Lactose: Milk, yogurt, ice cream, soft cheeses (cottage and ricotta cheese)
- Excess Fructose: High fructose corn syrup, honey, agave, and various fruits like apple, pear, and watermelon
- Polyols: Stone fruits (like peach, plum, cherry), mushrooms, cauliflower, and the sugar alcohols listed above

Some of the foods that **are allowed** on a low FODMAP diet are:

- Grains: rice, oats, gluten-free pasta, some gluten-free breads and cereals
- Fruits: berries (except blackberries), orange, banana, grapes, honeydew or cantaloupe melon, kiwifruit, pineapple
- Vegetables: Carrots, corn, eggplant, zucchini, peppers, green beans, lettuce, cucumber, potato, and tomato are a few.
- Protein: Chicken, turkey, beef, pork, fish, eggs, tofu, peanut butter; avoid meats that are seasoned with onion/garlic powder
- Dairy: Lactose free milk, almond milk, kefir, lactose free yogurt, hard or ripened cheeses like cheddar and feta

The low FODMAP diet has a high success rate when taught by a Registered Dietitian (RD) with expertise in this diet. It is a two-part diet consisting of elimination and challenge (reintroduction) phases. Patients who try this diet on their own usually find it too restrictive. They may also be choosing the wrong foods and not feel the relief in GI symptoms that would be expected. The Registered Dietitian will guide you to eat nutritious and tasty meals that suit your palate and agree with your gut. There are many variables to this diet and to maximize the foods that can be eaten, it is **strongly** recommended that patients consult with a Registered Dietitian who is familiar with the low FODMAP diet.

What can I expect at an appointment with the Registered Dietitian (RD)?

- Learn about the low FODMAP diet approach and why it is effective
- Receive comprehensive low and high FODMAP food lists from updated sources
- Guidance on implementing the low FODMAP diet taking into account your other medical conditions
- Individualized menu planning tailored around your life schedule and cooking skills
- Label reading and grocery shopping tips for eating a low FODMAP diet
- Confidence that you can eat a nutritionally sound diet following the low FODMAP diet.

At Michigan Medicine, a consult with a dietitian familiar with the low FODMAP diet can be made at the following locations:

Taubman Center Gastroenterology Clinic: 734-647-5944

East Ann Arbor Health and Geriatrics Center: 734-647-5655

Northville Health Center: 248-305-4400

Brighton Health Center: 810-227-9510



Are there foods I should avoid?

Many people with IBD are not able to tolerate certain foods. A food diary can help you figure out which foods bother you. Be sure to try foods that gave you trouble in the past to make sure it was the food, not just a change in your IBD.

Many people find that caffeine and alcohol increase their symptoms of IBD. Caffeine speeds up intestinal motility (the movement of food through the digestive tract) and can cause diarrhea even among people with healthy intestines. Alcohol in large amounts can induce flares of IBD. College students with IBD often prove this during their freshman year. Use common sense. Most people with IBD are able to tolerate moderate amounts of caffeine and alcohol in their diet.

A food diary can also show if your diet is providing the nutrients your body needs. You and your dietitian can review your food diary to be sure that you are getting the recommended daily allowances (RDAs) for a person of your age, sex, and size. If not, the dietitian can suggest ways to change your diet so that you get what you need. That may mean increasing the amount of food you eat, changing what you eat, or adding vitamins or minerals to your diet.

Everyone needs enough calories, proteins, and nutrients in their diet. A balanced diet includes a variety of foods from all food groups. Meat, fish, poultry, and dairy products are sources of protein; bread, cereal, starches, fruits, and vegetables are sources of carbohydrate; butter and oils are sources of fat.



Do I need to avoid milk and dairy?

Generally no. Lactose intolerance is not a part of IBD, so most people with IBD do not have to avoid foods that contain lactose (milk and dairy). Some people, especially those of Asian or African backgrounds, cannot tolerate lactose as they get older. However, they can often handle small amounts of dairy in their diet, and by taking lactase tablets with dairy foods they can often tolerate even more. Some people with Crohn's disease have severe flares that involve the duodenum (the first part of the small intestine), where lactose is digested. This inflammation

can damage the lining of the intestine, and cause lactose intolerance for 1 to 3 months. This will resolve as the intestine heals.

This does not happen to people with ulcerative colitis or Crohn's colitis (Crohn's disease affecting only the colon) because the small intestine is not involved. If you think you are lactose intolerant, talk to your doctor. A lactose breath test, which is easy to do, is used to make the diagnosis. Your body needs dairy products because they provide calcium and vitamin D, as well as protein. Unless you have been told you have lactose intolerance, there is no reason to avoid milk and dairy products.



Do I need to avoid fiber?

About 70% of people with Crohn's disease of the small intestine get a stricture (narrowing) of the intestine. When this happens, a low-fiber or low-residue diet may help to ease abdominal pain and other symptoms. This diet reduces the amount of food that cannot be digested (solid residue) in the stool. Foods to avoid include seeds, raw fruits, and vegetables; especially apple peels and stringy roughage, like celery. These fibers are not digested and can tangle into a net and block or slow down the passage of other food through the part of the intestine with the stricture. You will learn more about this diet at your clinic visit. It is likely that these changes in your diet will only be needed for a short time until the inflammation that caused the narrowing goes away.

It is important to note that many people with IBD do not have to worry about eating fiber, because they will not get strictures.



What about vitamins and minerals?

It is a good idea for all people with IBD to take a standard multivitamin every day. People with IBD who are doing well do not need any extra vitamins or minerals. If the disease is in the ileum (the last part of the small intestine) or if the ileum has been removed, it may be hard to absorb vitamin B12. Blood levels of vitamin B12 should be checked before you start to take a B12 pill. Certain medicines (sulfasalazine and methotrexate) can hinder the body's ability to make folic acid (a B vitamin). If you take these medicines, you also need to take a 1 mg folate tablet every day. Vitamin D is absorbed in the small intestine. About 80% of people in Michigan have low vitamin D levels because sunlight helps the body make vitamin D, and Michiganders sure don't get enough of that! Vitamin D is needed to absorb the calcium from the diet, so it helps keep bones strong. A vitamin D tablet in the range of 800 to 1,000 international units (IU) per day is needed, especially for those with active IBD and who live in the northern parts of the country.

Low iron levels are fairly common among people with IBD. It is caused by blood loss during inflammation, and by reduced iron absorption as a result of inflammation. Blood iron levels are easily measured. Low iron levels are treated with iron tablets or liquid. Taking iron by mouth often turns the stool black, which can be confused with intestinal bleeding.

Other possible problems include low levels of potassium and magnesium. Low potassium levels may be caused by diarrhea or vomiting or as a result of prednisone treatment. Potassium supplements are available in tablet and other forms. Oral magnesium oxide may be needed by people who have low levels of magnesium. A lack of magnesium can be caused by chronic diarrhea, a large amount of inflammation in the small intestine, or after a large amount of the intestine is removed. People with IBD who include very little calcium in their diets can have low calcium levels. This is most common when people avoid dairy products because they are lactose intolerant or because they think they are lactose intolerant. It can also happen to people who have enough calcium in their diets but do not absorb it as they should because of intestinal inflammation or because a large amount of the small intestine has been removed. In addition, medicines used to treat IBD may have a harmful effect on bone health. Long-term use of prednisone and other steroids, for example, slows the process of new bone formation and quickens the breakdown of old bone. It also interferes with calcium absorption. In addition to steroid use, Crohn's disease itself has been shown to be linked with bone thinning or osteoporosis. Therefore, screening with bone density studies (DEXA) is suggested for those at risk. People with bone loss should avoid steroids as much as possible to improve bone health. These people need to aim for at least 1,500 mg of calcium daily, either in food or in a pill taken three times during the day. Vitamin D needs to be taken along with the calcium so the calcium is absorbed. Pills with both calcium and vitamin D are widely available over the counter.



Should I change my diet during a flare?

It is common to find that you have a hard time tolerating food during a flare. During a period of active inflammation, any food can make pain, bloating, cramping, and diarrhea worse. However, you still need to eat during a flare. You also need to drink plenty of fluids with salt and water so that you absorb and retain fluid. You need to drink enough so that your urine is nearly clear most of the time. If your urine is very yellow or you are not making much urine, you are likely dehydrated. Becoming lightheaded when you stand up quickly is a sign of severe dehydration. If this happens to you, drink additional fluids. If it does not get better, call your doctor or nurse or go to the nearest emergency room.

Although it may be hard to keep up your normal (about 2000 calories) intake when you are feeling poorly, eating at least some food (about 1000 calories) will help maintain the cells in the lining of your gut and also help heal ulcers. Many people switch to a bland diet or to an all-liquid diet during a flare. Bland foods like rice, toast and nutritional drinks like Carnation[®] Instant Breakfast[™], Boost[®], or Ensure[®] can help keep your caloric intake over 1,000 calories per day. A bland or all-liquid diet is only used during a flare. After a flare, slowly restart your normal diet (not a triple cheeseburger on the first good day). In the long term, be sure to eat a balanced diet with a wide variety of healthy foods to maintain your health.



What is an elemental diet?

An elemental diet is made up of liquids with all of the nutrients you need, including amino acids, fats, sugars, vitamins, and minerals. This diet can be taken by mouth in the form of products you can buy over the counter (for example, Ensure[®]). This diet can also be given parenterally. This means it is given either IV (intravenously) or through a gastric feeding tube

placed through the skin into the stomach. People with severe Crohn’s disease may require this type of treatment to avoid malnutrition during a severe flare. The goal is to allow the gut to rest and heal before it has to deal with whole foods again.

Diet suggestions in IBD

Although there is NO SPECIFIC DIET to prevent or treat IBD, there are diets to help you control your symptoms. Different diets are used during a disease flare than during remission.

What to Eat When in a Flare

This handout provides suggestions for what to eat when you are experiencing active inflammation and increased symptoms related to your Inflammatory Bowel Disease. Once your intestines have healed and symptoms have calmed down, you may slowly reintroduce foods and **ultimately resume your normal diet.**

General Tips:

- Eat small frequent meals (5-6 per day) to ease GI symptoms and maximize calorie intake
- Avoid spicy foods and fried/greasy foods
- Try lactose free dairy products
- Reduce fiber intake
- Consume a high protein food at each meal/snack
- If you are having trouble getting enough calories, consume liquid oral supplements (such as Ensure Plus®, Ensure Original®, or Ensure Clear®) or make your own smoothie
- If you are in a flare and have a history of strictures (narrowing in the bowel), a liquid diet may be recommended to prevent an obstruction. Contact your doctor to discuss further.

The following chart includes suggested foods (foods that may be easier to tolerate during a flare) and foods to limit/avoid (foods that may exacerbate symptoms), taking into account the general tips provided above. The recommended foods are also low in FODMAPs (**F**ermentable **O**ligo-, **D**i-, **M**onosaccharides **A**nd **P**olyols). FODMAPs are gas producing and osmotic (draws water into the intestines) carbohydrates which can contribute to diarrhea, bloating, and discomfort. Please note: These are *suggestions* of foods to try. Tolerance to foods can vary from person to person.

| | Limit/Avoid | Recommended |
|--------------|--|--|
| Dairy | Milk, yogurt, ice cream, soft cheese (cottage and ricotta cheese), soy milk, rice/coconut milk | Lactose free milk (such as Lactaid®), almond milk, lactose free yogurt, kefir, lactose free ice cream, lactose free cottage cheese, and any hard/aged cheeses *Lactaid milk or equivalent is preferred over rice/coconut milk as it is higher in protein and calories. |

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| | | |
|---|--|--|
| Grains/starches | Wheat products (bread, pasta, crackers, cookies, bagels, some cereals), high fiber grains: brown rice, oatmeal, quinoa, corn/popcorn | White rice, gluten-free rice pasta and breads, rice crackers (without onion/garlic seasoning), rice chex or corn chex cereal, plain Cheerios, sweet or white potato without skin, corn tortillas, corn flakes, rice cakes, cream of rice hot cereal |
| | Limit/Avoid | Recommended |
| Vegetables | Raw vegetables including salads; onion, garlic, artichokes, asparagus, cauliflower, sugar snap peas, mushrooms, celery | *Cook all vegetables to decrease fiber and avoid thick skins/peels. Limit to ½-1 cup per meal. Carrots, green beans, zucchini, broccoli, peppers, spinach, eggplant, tomato, green peas, olives |
| Fruit | Apples, pears, grapefruit, peaches, cherries, nectarines, apricots, plums/prunes, dates, persimmon, watermelon, blackberries, mango, dried fruit | *Limit to ½-1 cup serving per meal/snack. If needed, cook the fruit to decrease fiber or try blending in a smoothie with lactose free yogurt. Peel fruits with thick skins. Banana, blueberries, strawberries, cantaloupe, grapes, papaya, honey dew melon, pineapple, clementine, orange, kiwi, lemon/lime |
| Proteins *Try to include protein at each meal | Fried meats, sausage, bacon, fatty cuts of beef, raw nuts, beans | Lean meats (chicken breast, turkey, lean beef such as ground sirloin/tenderloin, fish, shellfish, pork tenderloin-such as shredded slowcooker pork), peanut/almond butter, eggs, tofu, tempeh, and lactose-free dairy products, whey protein isolate powder (99% lactose free), rice protein powder |
| Seasonings | Spicy food, onion, garlic (powder and fresh), honey, agave, high fructose corn syrup | Salt, pepper, lemon, soy sauce, fresh or dried herbs as tolerated |
| | Soda and drinks with high | Water, decaf coffee/tea, |

| | | |
|--|---|---|
| Beverages | fructose corn syrup (including Powerade), regular caffeinated coffee/tea, apple juice | Gatorade, lemonade made with real sugar (8oz limit per meal/snack), orange/cranberry/grape juice as tolerated (1/2 cup limit per meal/snack), lactose free milk, Ensure® (Original, Plus, Clear), homemade smoothie |
| Other | sugar-free gum and candy, large portions of concentrated sweets/desserts | |
| Sample Menu Day 1: | | |
| <p>Breakfast: Rice chex with lactose free 2% milk</p> <p>Snack: 2 scrambled eggs</p> <p>Lunch: Roasted turkey sandwich with cheese and mustard on gluten-free bread. 1/2-1 cup grapes</p> <p>Snack: rice cake with peanut butter</p> <p>Dinner: 3-4oz grilled chicken (not heavily seasoned), 1/2 cup well-cooked carrots, mashed potatoes made with butter and lactose free milk</p> <p>Snack: Lactose free yogurt topped with strawberries</p> | | |
| Sample Menu Day 2: | | |
| <p>Breakfast: 2 egg omelet with cheese and cooked veggies (red pepper, spinach, tomato, etc)</p> <p>Snack: Gluten-free toast with peanut butter</p> <p>Lunch: 1 cup gluten-free rice pasta with ground sirloin and homemade tomato sauce (without onion/garlic)</p> <p>Snack: banana</p> <p>Dinner: 3-4oz grilled fish, white rice, 1/2 cup sautéed zucchini and yellow squash</p> <p>Snack: Ensure Original®</p> | | |

Complementary and Alternative Medicine and IBD

Is there a cure for IBD that I can find on the Internet?

No. Lots of time and money is spent on IBD research. There is no real cure or treatment that you can buy on the internet or that is advertised on late night TV infomercials. That said, experts have a lot to learn about natural, herbal, and alternative therapies. Some new alternative treatments for IBD are being studied at the University of Michigan.

Why does the person at the local organic food store or nutrition supply shop tell me that herbal products will work for my IBD?

Diet supplements are a multibillion-dollar business in the United States. The Food and Drug Administration (FDA) is not allowed to regulate these products as long as they do not make specific health claims. Any supplement that claims it will reduce inflammation in Crohn's disease or ulcerative colitis would be taken off the market. Most of the products are said to have "some benefits" for digestion or keeping your bowel movements regular.

The people who work in these stores are sometimes paid extra when they sell supplements. They will often guide people to products that pay the highest rates, to add to their own pay. In contrast, your doctor does not receive money from drug companies for medicines you are prescribed.

Are supplements dangerous?

Many of these products do not work and are harmless but cost a lot of money. It is easy to spend so much on these products that you cannot afford the medicines that have been clearly shown to work for IBD.

Some products do have active components. While these may help, they can also be very harmful. For example, many can cause constipation. Others may interact with your other medicines and increase your risk for severe side effects. Some supplements work because they have ingredients that are not listed on the label, such as steroids. These "secret ingredients" may have very harmful side effects.

In addition, many supplements are not tested or controlled by the Food and Drug Administration (FDA). Some of these have had poisons or toxins (for example, mercury or lead) but it was not known until people became ill or died. Also, the suppliers can change the formula without any warning or regulation, which may lead to new side effects. It is important to know that some of these companies take advantage of people who want to get better. The FDA was created in 1913 to keep the public safe, but food supplements are not monitored by the FDA.

Please tell your doctor if you are taking supplements and which ones you are taking. Certain products that contain echinacea, cats' claw, and alfalfa are known to interact with many medicines used to treat IBD. They interfere with their action or increase the likelihood that you will have side effects.



Can probiotics help IBD?

Probiotics are now broadly marketed with little or no proof to support their use. A few probiotics have been tested and can be obtained with a prescription. One example is VSL #3, a probiotic that has been shown to help prevent pouchitis after a colectomy. However, most probiotics have not been shown to work for Crohn's disease or ulcerative colitis.

In addition, probiotics have been shown to be harmful in rare cases for people who are very sick. One well-done study of probiotics used in people with severe acute pancreatitis was stopped early because those taking probiotics were dying at a much higher rate than those taking the placebo. The lesson here is to be very careful with probiotics especially during active intestinal disease. It seems likely that live bacteria could cross intestinal ulcers through the wall of the intestine and get into the bloodstream, which could lead to serious infections. People who are also taking immunosuppressive medicines at the same time are at increased risk. This is because immunosuppressive medicines can make it harder for your body to fight infections.

A lot of probiotic research is now being done and some probiotics may be shown to be safe and effective for IBD in the future. At this time, trying probiotics on your own may not be wise, especially if you are taking immunosuppressive medicines or if you have active disease. VSL 3# is the only probiotic that has been shown to be of benefit for some people in order to prevent pouchitis after a colectomy.



Can fish oil help IBD?

Fish oil, which is high in omega-3 fatty acids, may be of some benefit at high doses for heart disease. However, two large randomized trials showed no benefit in Crohn's Disease. On the plus side, few side effects have been seen for those with Crohn's disease taking fish oil, although some people notice a fishy body odor or taste when they take high doses. In animal studies, these oils seem to have some benefit for the immune cells. However, clinical studies have not always found the same effect in people.

Also, there is no way to know if the capsules you buy actually contain fish oil, due to the lack of FDA oversight. It may be cheaper and safer to eat cold-water fish that are high in omega-3 (for example, salmon, mackerel, herring) 2 to 3 times a week than to pay for fish oil capsules.



Can aloe vera help IBD?

One small clinical study with 44 people who have ulcerative colitis showed that aloe vera gel (100 mL) taken twice a day for 4 weeks had a modest benefit. This good effect has not been shown again, but it still may be of benefit. The form of aloe vera gel used in the study is not the same as what is usually sold in stores. Aloe vera juice, which is often seen, has a laxative effect and is therefore a problem for people who have diarrhea. Side effects of aloe vera include bloating, foot pain, sore throat, ankle swelling, acne, and eczema.

Aloe latex (may be called aloe juice) contains strong laxative compounds. At one time, the FDA regulated laxative products with aloe as over-the-counter (OTC) laxatives. In 2002, the FDA ruled that all OTC aloe laxative products be removed from the U.S. market or be made without the aloe latex because the companies did not provide the needed safety data. At this time,

aloe products are not regulated by the FDA so it is hard to tell whether a product truly contains aloe vera gel or the laxative aloe latex.



Can bowel cleansing (high colonics or cleansing enemas) help IBD?

No. There is no evidence that purging the colon can help IBD. A study done at the University of Michigan showed that patients with ulcerative colitis who cleaned out their colons for a colonoscopy were more likely to have a minor flare of symptoms in the following 2 weeks. These flares were more common for those who needed steroids to control their symptoms. There is no proof of benefit and when the colon is inflamed, colon cleansing may be mildly harmful.



Where can I get good information about alternative therapies for IBD?

The best source is the National Center for Complementary and Alternative Medicine, which is funded by the National Institutes of Health. This is the web address: <http://nccam.nih.gov/>.

GI Behavioral Health Program

Why see a behavioral health psychologist?

When you or someone close to you is diagnosed with a chronic illness such as Crohn's Disease or Ulcerative Colitis, many challenges can occur beyond the physical symptoms. Taking care of your mental well-being is equally as important as taking care of your physical well-being. Unfortunately, in today's medical world, there often isn't time to address the social and mental effects of living with a chronic illness every day. This is where meeting with a health psychologist can be helpful. In fact, there are behavioral health therapies, such as cognitive behavioral therapy (CBT) for chronic GI disorders or medical hypnotherapy (gut-directed relaxation) for IBD that can treat your illness symptoms. These interventions are beneficial to complement your medical treatment.

What is the GI Behavioral Health Program at Michigan Medicine?

Behavioral health services are provided by a licensed clinical psychologist who has a unique understanding of the psychosocial issues specific to gastrointestinal disorders. Dr. Megan Riehl uses the most up-to-date, scientifically based treatments to assist you with managing your condition and improving your quality of life. She provides a safe, comfortable therapy environment (within the Taubman Center) where treatment is designed to help you feel better both mentally and physically. Treatments are designed for people who do not necessarily have a mental health problem, rather for people who want to better manage their physical condition.

You may be a good candidate for our services if you find that life stressors make your symptoms worse, you are excessively worried about the impact of your symptoms, you have trouble understanding your condition or treatment plan, your medicine is not working, you have trouble relaxing, you are experiencing anxiety or depression because of your symptoms or you feel as though you do not have an adequate support system. Psychological interventions that address stress and, in some cases, intestinal symptoms directly, can be beneficial for your gastrointestinal health and emotional well-being. The patient and Dr. Riehl will work collaboratively on a treatment plan that may include CBT, relaxation training, gut-directed hypnosis and stress-management training.

What will happen at my first appointment?

Your first visit will be an initial comprehensive consultation, which is designed for Dr. Riehl to learn about what brings you in for treatment and for you to ask any questions you may have. Initial consultations usually take about 60 minutes to complete. Since CBT is a collaborative effort between the psychologist and patient, during this visit you will begin to discuss your customized treatment plan that will address your specific treatment goals. You will also decide on how frequently you will come for visits (most people come once a week) and have an idea of how many visits you'll likely need. You will complete a New Patient Health Questionnaire to bring to your consultation.

What is Cognitive Behavioral Therapy?

Cognitive-Behavioral Therapy (CBT) is an evidence-based treatment that is used for many physical and psychological conditions. CBT is the most widely researched psychological treatment and has repeatedly been found to be effective for treating a variety of conditions including depression, anxiety, panic attacks, and many chronic illnesses. When you work with a psychologist who uses CBT, you will evaluate how you think about yourself, others and the world and identify which thoughts are helpful and which are not as helpful. By changing your unhelpful thinking patterns, your feelings and actions will also change.

CBT is an active exchange of information and ideas between you and your psychologist. Treatment is structured, problem-focused and directive. You will be asked to work on new skills that you learn in session during the time in between your appointments ("homework") and bring what you experienced on your own to your appointments to review and build upon. CBT is also designed to be time limited, with most people finding benefit after about 10-15 sessions. You may choose to stay in treatment longer to address other therapeutic treatment goals.

What is medical hypnosis?

Hypnotherapy was one of the first psychological therapies to be used in medical populations. It has been associated with positive outcomes in several chronic diseases such as cancer, fibromyalgia, chronic pain and others. Research has shown that gut-directed hypnotherapy is linked to improved function and health in the gastrointestinal tract. It has demonstrated efficacy in several gastrointestinal disorders, with treatment gains maintained for many years. Additionally, it has been shown that IBD patients receiving hypnotherapy have been able to prolong clinical remission.

Dr. Megan Riehl, is a licensed clinical health psychologist who specializes in the treatment of gastrointestinal problems and anxiety related-disorders. Working from a collaborative perspective, she believes that a strong therapeutic relationship will aid in facilitating change and improvements in quality of life. She has expertise in working with patients to manage the vast complexities associated with chronic diseases, such as IBD. Her approach relies on principles of cognitive-behavioral therapy, to design unique and flexible treatment plans tailored to the individual she is working with. Dr. Riehl received her master's degree in counseling psychology and doctorate in clinical psychology from Adler University. She completed a 2-year GI-health psychology fellowship in the Division of Gastroenterology and Hepatology at the Feinberg School of Medicine at Northwestern University. She is a clinical instructor on faculty in the Department of Internal Medicine at the University of Michigan.

Talk to your gastroenterologist about a referral to the GI Behavioral Health Program.



**Inflammatory Bowel Disease Program
Patient Information Guide**

My Information

Name _____ Registration Number _____

If any of your information changes, please call Hospital Registration toll free:

1-866-452-9896 • Monday to Friday 6:30 AM to 8 PM • Saturday 8 AM to 1 PM.

Primary Care Physician _____

Referring Physician _____

My Address

My Phone Numbers

| | | |
|--------------|--------------|--------------|
| Cell: | Home: | Work: |
|--------------|--------------|--------------|

Emergency Contact Names

Emergency Contact Phone Numbers

| | |
|-----------|--|
| 1. | |
| 2. | |

My Health Insurance and Pharmacy Information

| | |
|-------------------------------|--|
| Insurance Company: | |
| Insured Person's Name: | |
| Patient's Name: | |
| Group Number: | |
| Pharmacy Phone Number: | <i>Note: Ask your doctor for a 3-month prescription if you do mail order</i> |

Family and Friends Form

There is a law called HIPPA that forbids us from sharing your health information with anyone who is not authorized by you. The Friends and Family Form allows you to give permission for us to speak to your family members or friends about your care. You can print the Friends and Family Form from the internet and bring it to your next visit:

http://www.med.umich.edu/i/acs/healthcenters/waahc/documents/familyfriendsform_000.pdf

My Appointment Planner

| Date | Time | Appointment Type | Appointment Location | Do I need to bring outside records? | Refills needed? | Do I need a driver for this appointment? |
|------|------|------------------|----------------------|-------------------------------------|-----------------|--|
| | | | | Yes or No | Yes or No | Yes or No |
| | | | | Yes or No | Yes or No | Yes or No |
| | | | | Yes or No | Yes or No | Yes or No |
| | | | | Yes or No | Yes or No | Yes or No |
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| | | | | Yes or No | Yes or No | Yes or No |
| | | | | Yes or No | Yes or No | Yes or No |
| | | | | Yes or No | Yes or No | Yes or No |

My Medicines

| Medicine | Strength (example, milligrams or mg) | Number taken at a time (example, 2 tablets) | Frequency (example, 3 times per day) | Start Date | End Date | Why stopped? |
|-----------------|--|--|--|-----------------------|---------------------|-------------------------|
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Prednisone Taper Schedule

| Dose | Start Date | End Date | Number of Days |
|---------------------------------|-------------------|-----------------|-----------------------|
| ___mg prednisone by mouth daily | | | |
| ___mg prednisone by mouth daily | | | |
| ___mg prednisone by mouth daily | | | |
| ___mg prednisone by mouth daily | | | |
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| ___mg prednisone by mouth daily | | | |

Characteristics of My Inflammatory Bowel Disease

What type of IBD do I have?

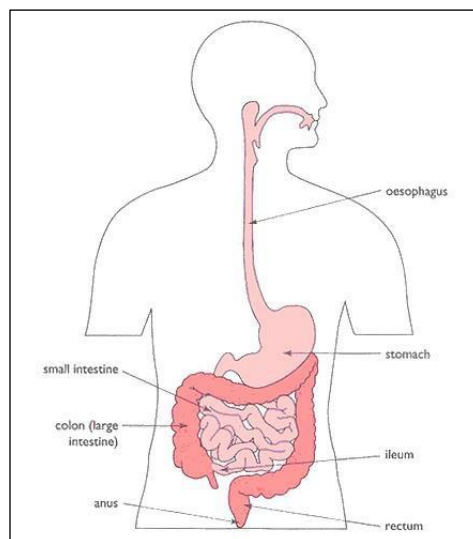
If you are not sure, ask your doctor. This is important for you to know.

- Ulcerative colitis
- Crohn's disease
- Indeterminate colitis
- I don't know

Where is the location of my IBD?

If you are not sure, ask your doctor. This is important for you to know.

| Segment of gastrointestinal tract | Yes | No |
|-----------------------------------|--------------------------|--------------------------|
| Esophagus | <input type="checkbox"/> | <input type="checkbox"/> |
| Stomach | <input type="checkbox"/> | <input type="checkbox"/> |
| Duodenum | <input type="checkbox"/> | <input type="checkbox"/> |
| Jejunum | <input type="checkbox"/> | <input type="checkbox"/> |
| Ileum | <input type="checkbox"/> | <input type="checkbox"/> |
| Ascending (right) colon | <input type="checkbox"/> | <input type="checkbox"/> |
| Transverse colon | <input type="checkbox"/> | <input type="checkbox"/> |
| Descending (left) colon | <input type="checkbox"/> | <input type="checkbox"/> |
| Sigmoid colon | <input type="checkbox"/> | <input type="checkbox"/> |
| Rectum | <input type="checkbox"/> | <input type="checkbox"/> |



Surgery on My Gastrointestinal (GI) Tract

| Date | Hospital name | Why was surgery done? | What segment(s) of intestine was removed? Length removed (in. or cm.)? | How was the intestine reconnected? |
|------|---------------|--|---|--|
| | | <input type="checkbox"/> Inflammation <input type="checkbox"/> Scarring or Blockage <input type="checkbox"/> Adhesions <input type="checkbox"/> Other | | <input type="checkbox"/> Not connected <input type="checkbox"/> ileostomy <input type="checkbox"/> colostomy <input type="checkbox"/> Connected <input type="checkbox"/> J pouch <input type="checkbox"/> _____ connected to |
| | | <input type="checkbox"/> Inflammation <input type="checkbox"/> Scarring or Blockage <input type="checkbox"/> Adhesions <input type="checkbox"/> Other | | <input type="checkbox"/> Not connected <input type="checkbox"/> ileostomy <input type="checkbox"/> colostomy <input type="checkbox"/> Connected <input type="checkbox"/> J pouch <input type="checkbox"/> _____ connected to |
| | | <input type="checkbox"/> Inflammation <input type="checkbox"/> Scarring or Blockage <input type="checkbox"/> Adhesions <input type="checkbox"/> Other | | <input type="checkbox"/> Not connected <input type="checkbox"/> ileostomy <input type="checkbox"/> colostomy <input type="checkbox"/> Connected <input type="checkbox"/> J pouch <input type="checkbox"/> _____ connected to |
| | | <input type="checkbox"/> Inflammation <input type="checkbox"/> Scarring or Blockage <input type="checkbox"/> Adhesions <input type="checkbox"/> Other | | <input type="checkbox"/> Not connected <input type="checkbox"/> ileostomy <input type="checkbox"/> colostomy <input type="checkbox"/> Connected <input type="checkbox"/> J pouch <input type="checkbox"/> _____ connected to |

Preventing Complications by Monitoring My IBD Medicines

If you take an immunosuppressive medicine such as azathioprine, mercaptopurine, or methotrexate, you will be enrolled in our monitoring program for people who take these medicines.

Lab tests (blood tests) will be done for as long as you take the medicine. This will usually include a complete blood count with differential and peripheral smear (CBC/D/P) and a comprehensive metabolic panel (CMP). These blood tests give us early clues about any side effects, such as a low white blood cell count (WBC) or increases in the liver function tests (LFTs). You will get baseline lab tests before starting to take the medicine. We will work together to make a plan for your blood work.

Please choose one lab for all of your blood tests, based on where you live and your health insurance. It will be easier if it is a University of Michigan lab. It is common to have lab tests done every 2 weeks for the first month, then monthly for 2 months as we figure out the best dose for you. Once you are taking a steady dose of the medicine and your blood tests are normal, you will have lab tests on a set schedule every 3 months.

If you take a 5-ASA medicine (for example, Asacol[®], Pentasa[®], Lialda[®]) your kidney function will be measured by a yearly blood test.

Preventing Infections with Vaccines

Vaccines are used to reduce our risk for infections. Some vaccines are made with a live virus and others are made with an inactivated form of the virus. Vaccines that are made with a live virus may cause some symptoms of the virus. However, they lower your risk for getting a more serious form of the infection.

People with IBD often need to take immunosuppressive medicines, which put them at increased risk for certain infections. People taking thiopurine medicines (like azathioprine [Imuran[®]] and mercaptopurine [Purinethol[®]]) are at a high risk for infections with viruses that stay in the body for a long time and become active again. For example, the virus that causes chickenpox can return much later in life as shingles. The virus that causes mononucleosis (Epstein Barr virus or EBV) can also become active again. The human papilloma virus (HPV), which contributes to cervical cancer, is more likely to cause an infection in women taking thiopurine medicines. People taking anti-TNF medicines, including infliximab (Remicade[®]), adalimumab (Humira[®]), and certolizumab pegol (Cimzia[®]), have a higher risk for diseases such as tuberculosis and histoplasmosis. There is also an increased risk for bacterial infections of the skin and soft tissues. Pneumonia is the most common, serious, and sometimes fatal infection that can occur while a person is taking an anti-TNF medicine.

Vaccines

The **pneumonia vaccine** (Pneumovax[®]) can protect people against 23 of the most aggressive types of pneumonia with just one shot. It is not a live vaccine and will not give you pneumonia. This vaccine is advised for all adults age 65 and older and also for **anyone** who is taking immunosuppressive medicines (including prednisone). A booster is given at 5 years.

The **flu vaccine** can prevent the flu or shorten the time the flu lasts and ease its symptoms. A flu shot is advised each fall for all people with IBD. Anyone who takes immunosuppressive medicines should get the shot and avoid the nasal spray. The shot is made of inactivated virus and the nasal spray is made of the live virus.

The **hepatitis B vaccine** is given to prevent severe infections of the liver. These infections can be more serious, and even fatal, among people who are taking anti-TNF medicines. This vaccine is now a part of the routine childhood shots. It is a good idea for everyone with IBD to get it because an anti-TNF medicine may be needed in the future. You need three (3) shots over 6 months for the vaccine to work. It often comes in a form that combines both hepatitis A and hepatitis B vaccines in a single shot (although it is still three [3] shots total). This vaccine is inactivated and safe to get while taking immunosuppressive medicines.

The **human papilloma virus (HPV)** vaccine (Gardasil[®] and Cervarix[®]) is recommended for young women between ages 11 and 26 to reduce their risk for cervical cancer. It is a good idea for young women with IBD to have this vaccine because taking an immunosuppressive medicine can increase your risk of HPV infection. A total of three (3) shots are required over 6 months for the vaccine to work. This vaccine is inactivated and safe to get while taking immunosuppressive medicines.

Chickenpox and shingles are caused by the same virus – varicella zoster. This virus lives on in the body after chickenpox and can occur again as shingles. Having the vaccine for both chickenpox and shingles is advised for adults. However, because these vaccines are made of the live virus, they are not safe for someone who is taking immunosuppressive medicines. It is best to have one of these vaccines at least 2 months after stopping an immunosuppressive medicine, and to not start taking immunosuppressive medicine for about 2 months after having one of these shots.

Injectable polio vaccine is not a live virus, and will not cause polio. This vaccine is advised for children. The oral form is a live vaccine and is not considered safe for people who take immunosuppressive medicines.

Vaccination plan

Childhood: MMR, polio, rotavirus, Hib, Tdap, chickenpox, and hepatitis A and B long before immune suppressed

Adolescence: meningitis, Tdap, hepatitis B, and Gardasil (for females).

At diagnosis of IBD: flu shot. If immunosuppressive medicine is not needed right away, consider pneumonia vaccine and shingles vaccine.

Other vaccines

In special situations, you may consider having these other vaccines:

| Situation | Vaccine |
|---|--|
| Veterinarians, animal handlers, cave explorers, or after an animal bite | Rabies |
| Anthrax laboratory workers, military personnel | Anthrax |
| Children (adults should have a Td booster shot every 10 years or deep wound. At least one of these booster shots needs to be Tdap). | Tdap(tetanus/diphtheria/pertussis) |
| Travel in Central or South America, Mexico, Asia (except Japan), Africa, and Eastern Europe; men who have sex with men; people who use street drugs; people with chronic liver disease; people treated with clotting factor concentrates; hepatitis A lab workers; also part of routine childhood shots | Hepatitis A |
| Children younger than 5 years; people without a spleen; people with sickle cell disease or HIV | Hib (Haemophilus influenza type B) |
| Travel in rural Japan | Japanese encephalitis virus* |
| Anyone born after 1956 | MMR* (measles/mumps/rubella) |
| College freshmen, military recruits, children, travelers to Africa, people with a damaged spleen | Meningitis |
| Babies | Rotavirus* |
| Military personnel | Smallpox* |
| Travel to Africa | Live typhoid* |
| Children and adults who have not had chickenpox Adults who are 60 or older | Varicella (chickenpox)* Varicella (shingles)* |
| Travel to areas with yellow fever | Yellow fever* |

Problems with live vaccines (planning ahead)

Many vaccines work better if they are alive but weak. They cause a better immune response. However, if you are taking an immunosuppressive medicine, these vaccines can cause infections. It is **VERY IMPORTANT** to avoid active virus vaccines while taking immunosuppressive medicines. The five vaccines that only come in live forms should be given at least 2 months before starting to take an immunosuppressive medicine (for example, prednisone, azathioprine, methotrexate, Remicade[®], Humira[®], Cimzia[®]). Live vaccines should not be given while you are taking immunosuppressive medicines, or within 2 months after these medicines are stopped. The inactivated form should be used instead whenever possible. If you are taking an immunosuppressive medicine tell your primary care doctor before you get any shots.

| Common live vaccines | Uncommon live vaccines |
|---|--|
| <ul style="list-style-type: none"> • Nasal spray (Intranasal) flu – remember the shot form is inactivated vaccine but the nasal spray is a live vaccine • Varicella (chickenpox and shingles) – • MMR (measles, mumps and rubella) – this vaccine is used in children only and as a booster for health care workers who have negative titer • Rotavirus – this vaccine is used in children only • Oral polio – this vaccine is used in children only the injectable polio vaccine, which is not live, is also good for children | <ul style="list-style-type: none"> • Smallpox • Yellow fever • Oral typhoid – can use injectable typhoid |

Vaccinations *** Live vaccine – not recommended while taking immunosuppressive medicines

| Vaccine | Date | Recommended |
|--|--|---|
| Influenza (flu) | <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ | Annually for everyone **If taking immunosuppressive medicine, only get the flu shot, which is inactivated, not the nasal spray, which is live. |
| Pneumovax® (pneumonia) | <input type="checkbox"/> _____ <input type="checkbox"/> _____ | Everyone 65 years and older, and at any age if taking immunosuppressive medicine Booster 5 years later |
| Hepatitis B | <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ | Everyone Series of 3 shots at 0, 1, and 6 months |
| Td or Tdap (tetanus, diphtheria, pertussis) | <input type="checkbox"/> _____ <input type="checkbox"/> _____ | Booster shot (Td) for everyone, every 10 years (at least once with Tdap for adults) |
| Varicella*** (chickenpox) | <input type="checkbox"/> _____ | If never had disease in childhood |
| Varicella*** (shingles) | <input type="checkbox"/> _____ | Advised for everyone 60 years and older to boost immunity |
| Oral typhoid*** Yellow fever*** | <input type="checkbox"/> _____ <input type="checkbox"/> _____ | Travelers to Africa, South America |
| Smallpox*** | <input type="checkbox"/> _____ | Military personnel |
| Meningitis | <input type="checkbox"/> _____ | College freshmen, military recruits |

Smoking and Inflammatory Bowel Disease

There is no doubt that smoking will make your Crohn’s disease much worse. It makes your symptoms worse and can make it harder for medicines to work. If you smoke and you have Crohn’s disease or ulcerative colitis, stopping is one of the best things you can do for yourself. It is hard to quit, but there is help. Talk to your doctor or attend a smoking cessation program for help in quitting.

If you have ulcerative colitis you may have a flare when you quit smoking. Using a nicotine patch can help to prevent or relieve the flare.

Smoking history

- I have never smoked.
- I previously smoked _____ packs per day for _____ years. I quit in the year _____.
- I currently smoke _____ packs per day. I have smoked for the last _____ years.

Tuberculosis (TB) and Hepatitis B Tests (required before taking an anti-TNF medicine)

| Date | Test | Results (negative or positive) |
|-------|---|--------------------------------|
| _____ | <input type="checkbox"/> TB skin test | _____ |
| _____ | <input type="checkbox"/> QuantiFERON® – TB blood test | _____ |
| _____ | <input type="checkbox"/> Chest x-ray | _____ |
| _____ | <input type="checkbox"/> Hepatitis B surface antigen | _____ |
| _____ | <input type="checkbox"/> Hepatitis B surface antibody | _____ |

Preventing Skin Cancer

People who have IBD and take immunosuppressive medicines such as azathioprine have an increased risk for basal cell and squamous cell skin cancers. There is no increased risk for melanoma. Using sunblock, especially in the summer and at any time you will be out in the sun will help lower your risk. If you take immunosuppressive medicines for a long period of time, you are advised to see a dermatologist for a complete skin exam.

Skin cancer prevention tracker

- I use sunblock daily/regularly.
- I do not use sunblock.
- I take azathioprine (e.g., Imuran®) or 6-mercaptopurine (Purinethol®).
- I have a yearly skin exam with a dermatologist.

| Date | Abnormal findings |
|-------|-------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

Preventing Bone Loss (osteopenia and osteoporosis)

What is osteoporosis and what causes it?

Osteoporosis is the loss of bone minerals such as calcium. It can lead to broken bones, often of the hips and spine. Other risk factors include a family history of osteoporosis, high alcohol intake, low calcium and vitamin D intake, limited physical activity, smoking, and age. The highest risk for osteoporosis is among women after menopause (natural or after surgery).

What is osteopenia?

Osteopenia is the milder stage of bone loss that occurs before osteoporosis. If you have osteopenia, you have a much higher risk for osteoporosis than if your bone density is normal. Children who have osteopenia are at high risk for osteoporosis in adulthood.

Why is vitamin D so important?

Your body needs calcium to make strong bones, and vitamin D plays a key role in helping your body use calcium. That is why many calcium pills also contain vitamin D. Vitamin D is made in the skin from the sun's ultraviolet rays. To make enough vitamin D, the skin needs to be exposed to sunlight for 15 minutes a day for a few days each week. While it is a good idea to use sunblock to prevent skin cancer, sunblock also prevents the skin from making vitamin D. People who live in the northern states are at increased risk for not getting enough vitamin D because of the long winters.

Why does IBD increase the risk for osteoporosis?

People with IBD who have decreased bone density are at increased risk for osteoporosis. They are also more likely to get osteoporosis at a younger age. The Crohn's & Colitis Foundation of America estimates that between 30 and 60 percent of patients with IBD have decreased bone density. Low bone density in IBD is caused by the general risk factors mentioned above, along with risk factors related to the IBD. These include chronic inflammation, side effects of medicines used for IBD (especially steroids like prednisone), low ability to absorb calcium and vitamin D, and lack of exercise during times of bed rest. Small bowel surgery and liver disease (such as primary sclerosing cholangitis) also increase the risk for low bone density. People who develop pouchitis (inflammation where the small bowel is connected to the anus) after surgery are also at risk for low bone density.

Why is it important to prevent bone loss?

Hip and spine fractures can greatly decrease the ability to walk and move around and to care for oneself. In the United States, 50 percent of women and 25 percent of men will have a fracture due to osteoporosis.

How is osteoporosis measured?

A bone density scan, also called a DEXA (dual energy x-ray absorptiometry) scan, is an x-ray that measures bone loss. It is the standard test for bone density. You doctor will order a DEXA scan when you are first diagnosed and periodically to monitor any changes. The goal of the test

is to see if you are at risk for osteoporosis so that you can get the help you need to treat or prevent osteoporosis.

This DEXA scan compares your bone density with bone densities of a large group of younger people. The test result is written as a T score. A T score between -1.5 and -2.5 represents osteopenia, which is the stage of bone loss that occurs before osteoporosis. Osteoporosis is a T score of less than -2.5 . Bone density is usually measured in the spine and hip (with the hip being the most important area). There is a different standard of measurement for children called a Z score.

Will I need any other tests to detect bone loss?

You may have a blood test to check your vitamin D level. The normal result is 30 to 74 nanograms per milliliter (ng/mL) for a 25-hydroxyvitamin D test. If your level is low, you may need to take vitamin D pills. The usual daily dose is 400 to 1,000 international units (IU), although older people need at least 1,000 IU per day. People with Crohn's disease may need up to 50,000 IU weekly for several months, and then maintenance with 4,000 IU daily.

What do I need to tell my doctor about my risk for osteoporosis?

- Any family history of bone fractures
- My history of bone fractures
- My history of steroid use
- My history of smoking
- My history of alcohol use (more than 2 drinks per day)
- If I have poor vision
- My use of a seat belt and bicycle helmet
- If I have a neuromuscular disorder
- Any medicines I am taking (for example, proton pump inhibitor [PPI] like Prilosec[®], heparin, Depo-Provera[®] [the birth control shot])

Treatments for low bone density

There are things you can do to treat low bone density and lower your risk for fractures. Some of the things you can do are to get regular weight-bearing exercise, such as walking or dancing, stop smoking, and make sure your diet gives you enough calcium and vitamin D. You may also take calcium and vitamin D supplements, or other medicines such as bisphosphonates, calcitonin, gonadal steroid hormone replacement, or parathyroid hormone therapy. Steroid medicines will only be used as needed and in the lowest dose possible to manage your IBD and keep your bones healthy.

- Calcium-rich foods include low-fat milk, yogurt, cheese, ice cream, sardines, salmon, shrimp, broccoli, collard and turnip greens, sesame or sunflower seeds, and dried figs. Some products, such as orange juice, are fortified with calcium.

For a comprehensive list of calcium content in foods, go to this web page:

<http://www.ars.usda.gov/services/docs.htm?docid=9673>

- Calcium pills – 1,200 to 1,500 mg/day.

- Vitamin D pills – 400 to 50,000 international units, as indicated.
- Daily weight-bearing exercise – such as jumping, running or weightlifting.
- Medicines
 - May be needed if you have osteoporosis or if you have had a broken bone in the past along with low bone density.
 - Mostly work to prevent further bone loss.
 - Bisphosphonates are usually used for women after menopause or for women with osteoporosis caused by steroid medicines. Alendronate (Fosamax[®]) or risedronate (Actonel[®]) are the most common for adults. Intravenous (IV) infusions or shots of biphosphonates may be used for people who cannot tolerate oral medicines or who have severe bone loss or fracture.
 - Teriparatide (Forteo[®]) – This medicine causes new bone to be formed. Teriparatide is a synthetic form of the parathyroid hormone. It is used by patients with multiple risks for fracture or who have had broken bones in the past. A bone specialist (endocrinologist) usually monitors this medicine, which can be used for up to 2 years.

Risks associated with treatment for osteoporosis

Most people with IBD are young, so the risk for fracture is usually low. Bisphosphonates are rarely used among women who could become pregnant because these medicines may affect the unborn baby. A rare complication of these medicines is osteonecrosis (dying bone tissue) in the jaw. This occurs most commonly with intravenous biphosphonates and at the same time as dental work, injury to the jaw, or infection. As much as possible, major dental work needs to be done before taking biphosphonates and avoided while taking biphosphonates.

Bone Health Tracker

Steroid (prednisone, Solu-Medrol[®]) History

I have taken steroids for _____ months of my life.

If you have taken steroids for more than 3 months, ask your doctor if you need a bone density scan (DEXA).

Vitamin D blood test results

| Date | Level |
|------|-------|
| | |
| | |

DEXA scan results

| Date | T score | Z score | Interpretation |
|------|---------|---------|---|
| | | | <input type="checkbox"/> Normal <input type="checkbox"/> Osteopenia <input type="checkbox"/> Osteoporosis |
| | | | <input type="checkbox"/> Normal <input type="checkbox"/> Osteopenia <input type="checkbox"/> Osteoporosis |
| | | | <input type="checkbox"/> Normal <input type="checkbox"/> Osteopenia <input type="checkbox"/> Osteoporosis |

Medicines used to increase bone density:

- Calcium: 1,200 to 1,500 mg by mouth daily
- Vitamin D: _____ international units (IU) taken daily, twice daily, or monthly (*circle one*)
- Bisphosphonates:
 - alendronate (Fosamax[®]): _____ mg taken daily or weekly
 - risedronate (Actonel[®]): _____ mg taken daily, weekly, or monthly
 - ibandronate (Boniva[®]): _____ mg taken daily or monthly
 - zoledronic acid (Reclast[®]): _____ mg taken yearly
 - other: _____ : _____ mg taken _____

Preventing Colon Cancer

Some people with IBD have a slightly higher risk for colon cancer than those without IBD. The exact risk is not known, but new studies suggest that the risk is lower than had been thought in the past. Not everyone with IBD has the same risk for colon cancer. Having a colonoscopy as often as advised can help to detect early signs of cancer or pre-cancer, when it can be treated most easily. Everyone with IBD in the colon requires a colonoscopy starting 8 years after the first symptoms of IBD, and then every 1 to 2 years.

Understanding your risk for colon cancer:

1. People with ulcerative colitis have an increased risk for colon cancer 8 to 10 years after diagnosis.
2. People with a limited form of ulcerative colitis that involves just the rectum do not have an increased risk for colon cancer.
3. Taking your IBD medicines regularly can help to decrease your risk. IBD medicines help reduce your symptoms and also decrease the risk for colon cancer.
4. Some medicines, supplements, and vitamins can have a “chemopreventive” effect, meaning that they protect a person from getting cancer. No medicine, supplement, or vitamin has been definitely shown to prevent cancer, but several show promise. These include IBD medicines related to mesalamine (Asacol[®], Pentasa[®], Lialda[®], Colazal[®], Azulfidine[®]) and folate (also called folic acid). Ask your doctor about new advances in this area.
5. If you have Crohn’s disease with inflammation in your colon you may be at increased risk for colon cancer. The most common type of Crohn’s disease is when it occurs only in the last part of the small intestine (the terminal ileum) and does not increase the risk for colon cancer.
6. Ask your doctor if you have an increased risk of colon cancer because you have IBD.

Preventing Colon Cancer Tracker

My colon is is not affected by IBD.

It has been _____ years since I started having symptoms of IBD.

- I have a family history of colon or rectal cancer.
- I have primary sclerosing cholangitis (PSC).
- I have had low-grade pre-cancerous cells (dysplasia) in the colon.
- I have had high-grade pre-cancerous cells (dysplasia) in the colon.

What part of my intestine is affected by IBD?

- Only the rectum is affected (no increased risk for colon cancer).
- The rectum plus the sigmoid and/or the left colon are affected (left-sided disease).
- The left colon, including the transverse colon and possibly the right colon, are affected (extensive disease).
- For Crohn’s disease:
 - less than one third of my colon is affected by Crohn’s disease
 - more than one third of my colon is affected by Crohn’s disease

Surveillance Colonoscopy Results

| Date | Result | Interval for next surveillance colonoscopy |
|------|--|---|
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |
| | <input type="checkbox"/> No dysplasia <input type="checkbox"/> Indeterminate <input type="checkbox"/> Low-grade dysplasia <input type="checkbox"/> High-grade dysplasia | 1 to 2 years 6 months, or when inflammation improved 6 months 3 months (colectomy preferred) |

Preventing Cervical Cancer (for women)

Risk factors:

- I no longer have a cervix OR I am older than 65.
- I am not taking any immunosuppressive medicines.
- I have been vaccinated for human papilloma virus (HPV).
- I have human papilloma virus (HPV) in my cervix.
- I have had an abnormal pap smear.
- I have had cervical cancer.
- I have never had a pap smear.

Pap Smear Surveillance Results

| Date | Result | Interval for next Pap smear |
|------|---|---|
| | <input type="checkbox"/> Normal, not taking immunosuppressive medicine <input type="checkbox"/> Normal, not taking immunosuppressive medicine, but abnormal Pap smear in last 5 years <input type="checkbox"/> Normal, taking immunosuppressive medicine <input type="checkbox"/> Abnormal | 3 years 1 year 1 year 6 months |
| | <input type="checkbox"/> Normal, not taking immunosuppressive medicine <input type="checkbox"/> Normal, not taking immunosuppressive medicine, but abnormal Pap smear in last 5 years <input type="checkbox"/> Normal, taking immunosuppressive medicine <input type="checkbox"/> Abnormal | 3 years 1 year 1 year 6 months |
| | <input type="checkbox"/> Normal, not taking immunosuppressive medicine <input type="checkbox"/> Normal, not taking immunosuppressive medicine, but abnormal Pap smear in last 5 years <input type="checkbox"/> Normal, taking immunosuppressive medicine <input type="checkbox"/> Abnormal | 3 years 1 year 1 year 6 months |
| | <input type="checkbox"/> Normal, not taking immunosuppressive medicine <input type="checkbox"/> Normal, not taking immunosuppressive medicine, but abnormal Pap smear in last 5 years <input type="checkbox"/> Normal, taking immunosuppressive medicine <input type="checkbox"/> Abnormal | 3 years 1 year 1 year 6 months |

Sexual Health and Childbearing Issues in IBD

Sexual Health

Can I have a normal sex life if I have Crohn's disease or ulcerative colitis?

Sexual health is an important part of your overall health and quality of life. Crohn's disease and ulcerative colitis can affect your sexual health. When the disease is active, you may feel very tired and have little desire for sex. Major abdominal or pelvic surgery (for example, removal of the colon) increases the risk for erectile dysfunction (impotence), which means not being able to have or keep an erection. Surgery can also affect body image and how a person feels about their desirability. Some people with Crohn's disease develop a fistula. If it is a fistula in the genital area, intercourse can be painful. Please talk to your doctor if you are concerned about any of these issues.

A sexually transmitted disease (STD) can make it harder to treat IBD. For example, if you get genital herpes while you are taking an immunosuppressive medicine, you may have to stop taking the medicine until the herpes is treated. Women with IBD who are taking an immunosuppressive medicine may have a higher risk for infection with the human papilloma virus (HPV). Many people are exposed to HPV, and in some women it causes cervical cancer. In addition to a yearly PAP test (PAP smear) and getting the HPV vaccine (see *Vaccines* in the section *Maintaining My Health*), always use condoms to protect yourself from STDs. Overall, when treated, patients with IBD have happy and healthy sexual activity. Treatment of your condition leads to increased energy level and interest in intimacy.

Fertility, Pregnancy, and Breast-Feeding with IBD

Can I have a baby if I have Crohn's disease or ulcerative colitis?

Yes, most women who have IBD are able to get pregnant and carry a baby to term. Having IBD does not reduce the chances you will get pregnant. The effect of IBD on pregnancy depends on how severe the disease was before and during pregnancy. If the disease is in remission at the time the baby is conceived, it will likely stay in remission during pregnancy. If your IBD is well controlled, you can expect to have a normal pregnancy. Women with more severe IBD have a greater risk of early delivery and of having a baby with low birth weight. This stresses the need for continued excellent control of IBD during pregnancy (see below).

Major abdominal or pelvic surgery increases the risk of not being able to get pregnant and may affect a woman's ability to carry a pregnancy to term. The most common problem is caused by the growth of scar tissue that blocks the fallopian tubes. If this occurs, in vitro fertilization may be an option. In men, major abdominal or pelvic surgery increases the risk for erectile dysfunction. Sulfasalazine, a common medicine used to treat IBD, causes a decrease in sperm count and fertility in 10% of men who take it. If you are taking sulfasalazine and your partner is having a hard time becoming pregnant, talk to your doctor about switching to another 5-ASA medicine. The sperm count will return to normal when the sulfasalazine is stopped.

Many medicines can be used during pregnancy, however you should talk to your doctor about how medicines will impact your pregnancy, fetus, or delivery prior to trying to conceive or when you realize you are pregnant. ONE MAJOR EXCEPTION is **METHOTREXATE**. You **must** not use methotrexate when trying to become pregnant or when you are pregnant. This medicine is clearly linked to spontaneous abortion and severe birth defects. You should use two methods of contraception when using methotrexate to avoid unintentionally becoming pregnant. Methotrexate should be stopped 6 months prior to attempting to become pregnant.

It does not appear that the risk for birth defects is higher if a man is taking azathioprine when his partner becomes pregnant. Both men and women should talk to their doctor about this risk if planning a pregnancy.

How can I make sure my IBD is well controlled before I get pregnant?

The best way to control your disease is to get regular care from your health care team and take your medicines faithfully and in the prescribed doses. Tell to your doctor about your symptoms and any side effects, so you can work together to find the best treatment that works for you. If your IBD is not treated using your maintenance medicines, the inflammation can get out of control very quickly. This increased inflammation causes your disease to get worse and you will have symptoms such as diarrhea, blood or mucous in the stool, and abdominal pain. If you have ever had a flare of your disease, you know these symptoms. Many people lose their appetite and are unable to gain or even maintain a healthy weight when they have these symptoms. Or, because they associate food with painful bowel movements or increased diarrhea, they stop eating. This is a big concern if you get pregnant during a disease flare. If you are not able to take in enough calories, your baby will not grow as it should. IBD that is not controlled may cause fistulas, abscesses, and perforations. These are severe and need special treatment and maybe even surgery. Surgery during pregnancy may harm both the mother and her baby.

Will I have to go to the doctor more often when I am pregnant?

If you are taking immunosuppressive medicines or having disease flares while you are pregnant, you will need to see your obstetrician and IBD doctor more often. Your baby's growth will be closely monitored by your obstetrician with ultrasound scans over the course of your pregnancy.

Will my IBD get worse when I am pregnant?

IBD does not always get worse during pregnancy. Women whose IBD is in remission when they get pregnant are likely to stay in remission. Women with active disease when they get pregnant are likely to have active disease during pregnancy. Therefore, many women try to conceive only when they are in remission. Some women notice their symptoms improve while they are pregnant. This is due to changes that occur in the mother's immune system so that her immune system will not attack the baby, which is made of foreign cells. Remember, experts believe that the key problem in IBD is that the body's immune system fails to "turn off," which leads to unchecked inflammation. As a result, many women with IBD seem to get better from the "turning off" of the immune system that normally happens in pregnancy. Some women have flares shortly after giving birth when the immune system returns to normal. Of course, symptoms do not improve for every pregnant woman with IBD.

Should I keep taking my medicines for IBD while I am trying to get pregnant or if I become pregnant?

You will do better if your disease is under control before and during pregnancy. Most medicines used to treat IBD are generally safe to take during pregnancy. Therefore, it is a good idea to keep taking the medicines to treat your IBD while you are pregnant. Stopping a medicine that is working to control your disease can make your IBD worse. A flare during pregnancy is a big risk to you and your growing baby. One of the things to think about is whether the effects of a flare are worse than the risk of side effects from the medicines. You and your doctor need to talk about the risks and benefits of using medicines during pregnancy before you try to get pregnant. If you find out you are pregnant, don't stop your IBD medicines. Call your doctor right away to discuss whether you should keep taking your medicines. Methotrexate is the only medicine that you absolutely cannot take during pregnancy.

Will IBD medicines harm my baby?

The U.S. Food and Drug Administration decides the safety level of drugs taken during pregnancy. Category A includes medicines like Tylenol[®], which have been shown to be of very low risk to the baby during pregnancy. Category B medicines are the next safest medicines to take. These are generally considered very low risk to the baby during pregnancy. Category C means there are no studies to show if the medicine is safe or not safe to take during pregnancy. However, the benefits of taking the medicine often outweigh the risks of not taking the medicine. Category D means that there is some proof that the drug causes problems during pregnancy. However, the benefit of taking the medicine may still outweigh the risk of not taking the medicine. Category X means the drug should **ABSOLUTELY NOT** be taken during pregnancy and should be stopped for several months before getting pregnant.

Examples of category B drugs used to treat IBD include sulfasalazine (Azulfidine[®]) and mesalamine (Asacol[®], Canasa[®], Lialda[™], Pentasa[®], Rowasa[®]).

Infliximab (Remicade[®]), is also category B, and has been safely used in pregnancy and during conception. Large studies are underway to determine whether Remicade, Humira, Cimzia, and other anti-TNF agents need to be stopped during pregnancy. Early studies have shown good safety. Many patients with moderate to severe IBD continue on these medicines throughout the entire pregnancy with good outcomes for themselves and their growing baby.

Prednisone and Entocort[®] are category C drugs that have been used in pregnancy and are thought to be safe.

Azathioprine (Imuran[®]) and 6-mercaptopurine (Purinethol[®]) are category D drugs. While the official ruling by the FDA is that these drugs are not recommended during pregnancy, they have been used by large groups of people and found to be of very little risk. These groups include people with kidney transplants, autoimmune liver disease, and IBD. These medicines are used throughout pregnancy to stay in remission and control symptoms. If you do not feel okay about taking these medicines, talk with your doctor. Together you will come up with the best and safest plan for you and your baby.

Methotrexate is Category X and that means that this drug should **NEVER** be used during pregnancy or the 6 months before trying to become pregnant. There is a very large risk for birth

defects if you use methotrexate during pregnancy. Special safety measures are always needed when using methotrexate during childbearing years. Double contraception is required while taking this medicine. This means that **both the man and the woman** need to use birth control. For example, condoms are used by the man and birth control pills or an IUD are used by the woman. This is also true for couples when only the man is taking methotrexate, because this drug can affect the sperm. Men who take methotrexate should also stop taking the medicine 6 months before trying to conceive with their partner.

Women with IBD often need antibiotics during pregnancy. Two common antibiotics are metronidazole (Flagyl[®]), a category B drug, and ciprofloxacin (Cipro[®]), a category C drug. Metronidazole is generally used during pregnancy instead of ciprofloxacin.

Diphenoxylate plus atropine (Lomotil[®]), a drug often used for diarrhea, is considered category C and should not be taken during conception and pregnancy. Loperamide (Imodium[®]), which is also used to treat diarrhea, is considered a safer choice because it is a category B drug.

Can I breast-feed my baby while taking my IBD medicines?

Some IBD medicines are safe to continue while breast-feeding. These include mesalamine, sulfasalazine, and prednisone. Talk to your doctor if you are taking azathioprine, 6-mercaptopurine, or anti-TNF medicines and plan to nurse your infant. Methotrexate is **NEVER** to be taken while breast-feeding. It may be better for you and your baby to continue your medicines and bottle-feed your baby.

Genetic Risk for IBD in Childbearing

Will my children get IBD?

Experts are still trying to figure out the exact cause of IBD. At this time there seems to be more than one cause. Your genes may play a role, and also other things such as infection. If you have Crohn's disease, the risk that your child will develop Crohn's disease is about 10%. If you have ulcerative colitis, the risk that your child will develop ulcerative colitis is about 5%. This means that although your children are at a higher risk for IBD than the general public, they are not likely to develop IBD. If your child has symptoms of IBD or is not growing as expected, tell your child's doctor that you have IBD.

Resources

University of Michigan Crohn's & Colitis Program Website

<http://www.med.umich.edu/ibd/>

The U-M Crohn's & Colitis Program website has many useful resources:

- Useful information about the diagnosis and the disease: www.med.umich.edu/ibdschool
- Facts about IBD for friends and families
- Facts for students with IBD
- A glossary of some of the medical terms we use when talking about IBD
- Details about clinical research studies
- Facts about IBD research at the University of Michigan, including the research web sites of our faculty members
- IBD Newsletter – a newsletter for patients published three times a year.
- Webcasts of lectures on IBD
- How to make an appointment (for patients)
- How to refer a patient for an appointment (for physicians)

University of Michigan Crohn's and Colitis Student Initiative

Meets monthly in Mason Hall during school year, Contact: ibdstudentgroup@umich.edu

IBD Visiting Professor Lecture Series – These lectures are recorded and can be played on iTunes and YouTube. Links to the webcasts, as well as links to the lectures on iTunes and YouTube are posted on the U-M Crohn's & Colitis Program web site.

iTunes video podcast (vodcast) <http://itunes.umich.edu>

- Click on Health & Medicine.
- Look under Health Topics.
- Find the IBD Visiting Professor Lecture Series or IBD School icons.
- Download the video podcast to view at your leisure.

1. YouTube

http://www.youtube.com/view_play_list?p=BAE565C028BD31B3

2. Webcasts on the U-M Crohn's & Colitis Program website:

<http://www.med.umich.edu/ibd/>

Crohn's & Colitis Foundation of America (CCFA)

The Crohn's & Colitis Foundation of America (CCFA) is the largest grassroots organization devoted to curing Crohn's disease and ulcerative colitis, and improving the quality of life of children and adults affected by these diseases.

The CCFA is a nonprofit, volunteer-driven organization with over 50,000 members and 40 chapters in the United States that:

1. Provides information and support groups for patients with Crohn's disease and ulcerative colitis.
2. <http://www.ccfa.org/living-with-crohns-colitis/find-a-support-group>
3. The Information Resource Center provides information, support, and guidance on Crohn's and colitis. Call between 9 AM and 5 PM eastern time on weekdays 1-888-MY GUT PAIN (1-888-694-8872). Interpreters are available for more than 20 languages.
Information about the **Local Chapter** is at <http://www.ccfa.org/chapters>
4. Maintains Disease Information web pages at <http://www.ccfa.org/info/resources/> with information about tests, medicines, and treatment options in IBD.
5. The Michigan Chapter runs an annual fundraising walk in the spring and an annual fundraising movie gala in the fall.
6. Puts together educational workshops and symposia, and a scientific journal, *Inflammatory Bowel Diseases*, to help medical professionals to keep pace with the newest research discoveries in IBD.
7. Funds cutting-edge studies at major medical institutions (often at the University of Michigan), and nurtures investigators with grants at the early stages of their careers.
8. Conducts a national research meeting each year, *Advances in IBD*, to promote the exchange of new research findings in Crohn's disease and ulcerative colitis.

Find out more at <http://www.ccfa.org>

Clinical Research at the University of Michigan

Get informed by visiting <http://www.med.umich.edu/ibd/studies>

Do you want to find out about clinical research studies at the University of Michigan? The IBD clinical studies at the University of Michigan can be found at

<http://www.med.umich.edu/ibd/studies>

This clinical studies website has an up-to-date listing of what studies are currently enrolling, who can participate, where the study will be conducted, what participants will be asked to do as part of the study, whether compensation is offered, and who to contact for more information.

If you are not sure if you qualify for a particular study and would like to learn more, contact the clinical research staff in the U-M Crohn's & Colitis Program:

Either by email: higginsSCteam@umich.edu

Or by phone:

Jennifer Dixon 734-615-4843

Kelli Porzondek 734-764-0507

Anna Romans 734-615-7977

Kay Sauder 734-647-2564

Angie Theil

Recommended Books about Inflammatory Bowel Disease

▪ ***Crohn's and Colitis: Understanding and Managing IBD***

Hillary Steinhart, MD, MSc, FRCP(C)

Paperback: 224 pages

Publisher: Robert Rose; 1st edition (April 20, 2006)

Description: *Crohn's and Colitis: Understanding and Managing IBD* is written by a leading expert in the field and provides the most current and important information on these conditions. The book answers important questions and covers topics such as:

- What is inflammatory bowel disease?
- What are the symptoms?
- How do you get Crohn's disease or ulcerative colitis?
- What to expect when you have IBD?
- Dietary treatment
- Drug therapy
- Surgery
- Psychological factors
- Children with IBD, and
- Alternative medicinal therapies.

Learning as much as possible about your condition is an important step toward taking charge and relieving the negative effects of IBD on daily life. This book will give you a better understanding of diagnosis and treatment and help you to lead a useful and productive life. While there is no cure at this time, Dr. Steinhart's expertise and practical advice will go a long way to improve health and quality of life and provide hope to your loved ones.

▪ ***Crohn's Disease and Ulcerative Colitis: Everything You Need to Know***

Fred Saibel, MD

Paperback: 224 pages

Publisher: Firefly Books

Description: Inflammatory bowel disease (IBD) includes two chronic conditions, Crohn's disease and ulcerative colitis. It has remained for too long the secret illness no one wants to admit to having, let alone discuss. One percent of North Americans have IBD, yet its cause is unknown and there is no known cure.

Revised, updated and expanded, *Crohn's Disease and Ulcerative Colitis* is the complete practical guide for anyone dealing with inflammatory bowel disease. Dr. Fred Saibil, a renowned expert on IBD, provides concise and current practical information on Crohn's disease, ulcerative colitis, and related conditions. There is an entirely new chapter on self-management of IBD, with 7 added tables and drawings to guide you.

Crohn's Disease and Ulcerative Colitis includes important information on:

- Why people get IBD, including the hygiene hypothesis, and new genetic data

- Diagnostic methods, including enteroscopy, capsule endoscopy, CT, MR, and PET scans
- Effects of diet, including foods and food components that can cause diarrhea and gas
- Surgical options
- The expanding choice of drugs, plus probiotics and prebiotics
- Issues specific to children with IBD
- Effects on sex, child-bearing and drug usage during pregnancy and breast-feeding
- Self-management -- how to help your medical team help you
- How to take care of your bones
- How to cope with being in hospital.

For people with IBD, their relatives, and their caregivers, this book explains the plain facts about a disease that seriously affects the daily lives of so many.

▪ ***IBD Self-Management: The AGA Guide to Crohn's Disease and Ulcerative Colitis***
Sunanda V. Kane, M.D. MSPH

Paperback: 288 pages

Publisher: AGA Press (2010)

Description: Nearly 100,000 people in the United States of all ages will be diagnosed with inflammatory bowel disease (IBD) – Crohn's disease and ulcerative colitis – this year. Because IBD is a chronic condition, it requires a lifetime of daily self-management. Knowledge is the key to living well. Reviewed by the American Gastroenterological Association, and written in an easy-to-read style, this book offers advice from a trusted expert, Dr. Sunanda Kane, on all aspects of living with IBD. Readers learn the latest about symptoms and management; use of medicines and surgery; the role of nutrition, supplements, and specific foods and diets; IBD complications; how to increase fertility and have a healthy pregnancy; and, other ways that IBD affects people's lives. This book is for people of all ages, including parents concerned about growth in their children and teens with IBD.

▪ ***Learning Sickness: A Year With Crohn's Disease***
James M. Lang

Paperback: 187 pages

Publisher: Capital Books (VA) (July 20, 2005)

Description: *Learning Sickness* is the compelling narrative of Jim's battle with Crohn's Disease. Diagnosed at the age of 26, Jim spent the next five years coming to terms with how to live with a chronic illness. During that time, he fathered two children, earned a Ph.D., accepted his first teaching position, and began a writing career. Jim Lang provides a completely honest look at the way the disease can affect every aspect of a person's life: physical, emotional, and spiritual.

- *Pete Learns All About Crohn's and Colitis*

Hilarie and Joe Staton

Comic book

Publisher: Crohn's & Colitis Foundation of America (CCFA) (2007)

View and download this comic book from the following web page on the CCFA web site: <http://www.ccfa.org/info/brochures/ccfa.online.comicbook>

Useful Websites

- University of Michigan, Division of Gastroenterology: www.med.umich.edu/gi
- University of Michigan, Crohn's & Colitis Program: www.med.umich.edu/ibd/
- Crohn's & Colitis Foundation of America (CCFA): www.cdfa.org
- IBD School Videos: <http://www.med.umich.edu/ibd/school/index.html>
- Centers for Disease Control and Prevention: www.cdc.gov
- Needy Meds – for help with the cost of medicine: <http://www.needymeds.org/>
- Patient Assistance for Medicines: <http://www.med.umich.edu/ibd/>

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