

Remdesivir for Coronavirus Disease (COVID-19) (Outpatient)

What is remdesivir (Veklury)?

Remdesivir is a prescription medicine used to treat coronavirus disease 2019 (COVID-19) in adults and children 28 days of age and older and weighing at least 7 pounds (3 kg) who are:

• Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

It is not known if remdesivir is safe and effective in children under 28 days of age or weighing less than 7 pounds (3 kg).

Do not take remdesivir if you are allergic to remdesivir or any of the ingredients in remdesivir. See the end of this leaflet for a complete list of ingredients in remdesivir.

Before receiving remdesivir, tell your healthcare provider about all of your medical conditions, including if you:

- Have kidney problems
- Have liver problems
- Are pregnant or plan to become pregnant. It is not known if remdesivir can
 harm your unborn baby. Tell your healthcare provider right away if you are
 or if you become pregnant. Pregnancy registry: there is a pregnancy registry
 for individuals who receive remdesivir during pregnancy. The purpose of
 this registry is to collect information about the health of you and your baby.
 Talk with your healthcare provider about how you can take part in this
 registry.
- Are breastfeeding or plan to breastfeed. It is not known if remdesivir can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

remdesivir may interact with other medicines.

Especially tell your healthcare provider if you are taking the medicines **chloroquine phosphate** or **hydroxychloroquine sulfat**e as it may reduce the effectiveness of remdesivir.

How will I receive remdesivir?

• If you are not hospitalized: remdesivir is given to you through a vein by intravenous (IV) infusion one time each day for 3 days.

What are the possible side effects of remdesivir? Remdesivir may cause serious side effects, including:

- Allergic reactions. Allergic reactions can happen during or after infusion with remdesivir. Your healthcare provider will monitor you for signs and symptoms of allergic reactions during your infusion and for at least 15 minutes after your infusion. Tell your healthcare provider right away if you get any of the following signs and symptoms of an allergic reaction:
 - Changes in your heart rate
 - o Fever
 - Shortness of breath, wheezing
 - o Swelling of the lips, face, or throat
 - o Rash
 - Nausea
 - Sweating
 - Shivering
 - Increase in liver enzymes. Increases in liver enzymes are common in people who have received remdesivir and may be a sign of liver injury. Your healthcare provider may do blood tests to check your liver enzymes before and during treatment with remdesivir as needed. Your healthcare provider may stop treatment with remdesivir if you develop liver problems.
 - Nausea. The most common side effect of remdesivir is nausea.

These are not all of the possible side effects of remdesivir. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of remdesivir:

Medicines are sometimes prescribed for purposes other than those listed. You can ask your pharmacist or healthcare provider for information about remdesivir that is written for healthcare professionals.

What are the ingredients in remdesivir?

- Active ingredient: remdesivir
- Inactive ingredients:
 - Remdesivir for injection: betadex sulfobutyl ether sodium and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.
 - Remdesivir injection: betadex sulfobutyl ether sodium, Water for Injection, USP, and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.

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