HUM00221266 -- Tecovirimat (TPOXX®) Expanded Access

Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children

Email order to Pharm-IDS-RxBasket@med.umich.edu (preferred), or Fax to Research Pharmacy at 647-9302.

Medical team contact for questions (name, phone, and/or pager):

☐ Have ready for pick-up from UH B2 Pharmacy window by (date) ______________ (time) ______________
☐ Tube/Deliver to (ACP / CC Outpt / Other: ______________) by (date) ______________ (time) ______________
☐ Page when ready for pick/up or when tubed/delivered ______________
☐ Ship to patient. (Include Shipping Coversheet with prescription. Can only deliver Tuesday – Saturday.)

DIAGNOSIS:
| Non-Variola Orthopoxvirus Infection |

PROTOCOL: HUM00221266 / IND 116039 / CDC 6402

If applicable)

HEIGHT: N/A in cm (required) WEIGHT: __ lb kg (required) Use actual body weight

BSA: N/A m² (required, if applicable)

ALLERGIES: ☐ NKDA

HOLD FOR THE FOLLOWING PARAMETERS: [None for pharmacy to assess.]

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Weight (lbs)</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6</td>
<td>&lt;13</td>
<td>50 mg (¼ capsule) every 12 hours</td>
</tr>
<tr>
<td>6 to &lt; 13</td>
<td>13 to &lt; 28</td>
<td>100 mg (½ capsule) every 12 hours</td>
</tr>
<tr>
<td>13 to &lt; 25</td>
<td>28 to &lt; 55</td>
<td>200 mg (1 capsule) every 12 hours</td>
</tr>
<tr>
<td>25 to &lt; 40</td>
<td>55 to &lt; 88</td>
<td>400 mg (2 capsules) every 12 hours</td>
</tr>
<tr>
<td>40 to &lt; 120</td>
<td>88 to &lt; 264</td>
<td>600 mg (3 capsules) every 12 hours</td>
</tr>
<tr>
<td>120 and above</td>
<td>≥ 264</td>
<td>600 mg (3 capsules) every 8 hours</td>
</tr>
</tbody>
</table>

For oral therapy, no dosage adjustment is required for patients with mild, moderate, or severe renal impairment or patients with end stage renal disease requiring hemodialysis.

☐ All pages of the signed consent document have been scanned into MiChart Media tab.
☐ CDC intake form has been submitted to UM-Expanded-Access-Request@med.umich.edu.

HUM00221266 Tecovirimat (TPOXX®) 200 mg capsules (42 capsules/bottle)

Dose: _____ mg Frequency: (circle one) Every 12 hrs. OR Every 8 hrs.

Dispense: (circle one) 14-day supply OR _____ day supply (dispense full bottles)

Sig: Take * capsule(s) (= * mg) by mouth [Frequency Per Above] with a full glass of water within 30 minutes after eating a full meal of moderate or high fat (ideally about 600 calories and 25 grams of fat).

Auxiliary labels: Take with food.

☐ Check here if patient cannot swallow capsules or if dose <200 mg. Pharmacy will include CDC instructions for opening capsules and mixing with breastmilk, infant formula, milk, or food. The statement, “Follow included instructions for opening and mixing capsule(s) with milk or food,” will be added to the sig.

PI: Tejal Gandhi (12951). Dispensing Guidelines for current list of authorized prescribers.