Instructions for Opening and Mixing Tecovirimat Capsules with Food for Those Who Cannot Swallow Pills, Especially Infants and Children

INTRODUCTION

If your doctor prescribes tecovirimat for your child and your child cannot swallow capsules, the capsules may be opened to mix the contents with food to give a drug-food mixture. This sheet explains how to open the capsules and mix with breastmilk, infant formula, milk or food for infants and children. Each capsule of tecovirimat (also known as TPOXX®) gives 200 mg of drug. Your child’s dose is based on their weight. Infants who weigh less than 13 pounds should receive one-quarter (¼) of a capsule (50 mg). For infants who weigh 13 to under 28 pounds, the dose is half (½) of a capsule (100 mg). For infants who weigh 28 pounds or more, and older children, the dose will be in whole capsule(s). See the table below to locate the dose for your child and follow the corresponding instructions. Children who weigh 88 pounds or more receive the adult daily dose. Adults who are unable to swallow capsules may also use these instructions to open capsules and mix with food.

YOU WILL NEED

• 1, 2, or 3 tecovirimat capsules depending on weight (1 capsule = 200 mg of drug)
• 1 Tablespoon or an oral syringe that measures in milliliters (mL). If you have a small infant, a teaspoon is helpful.
• 1 small bowl
• 1 baby bottle, oral syringe that measures in mL, or spoon - for infants being given the dose by mixing with infant formula, breast milk, or milk
• One of these foods/liquids: infant formula, breast milk, milk, baby food or applesauce, yogurt, pudding, or chocolate syrup

DIRECTIONS FOR MAKING THE DRUG-FOOD MIXTURE

Step 1: Find your child’s weight in column A using the table on the next page. Use the information from the row with your child’s weight for the rest of the directions.

Step 2: Column B is information on the dose of drug you will be giving to your child. In order to prepare this dose, use column C to find the number of capsules you will need to prepare the dose and remove the correct number of capsules from the tecovirimat pill bottle.

Step 3: Hold the tecovirimat capsule with your fingers over a small bowl. Carefully pull the capsule open and pour out the contents (white powder) completely into the bowl. Look inside the capsule to make sure no powder is left inside the capsule. Repeat for additional capsules, if applicable.

Step 4: Add 2 tablespoons (30 mL) of food or liquid into the bowl containing the drug powder. Thoroughly mix the powder with food or liquid very well with a spoon. Ensure the prepared mixture is uniform. This makes the drug-food (or drug-liquid) mixture.

Step 5: Give the amount as directed in column E within 30 minutes of preparation. For infants, be sure to give the amount of the mixed formula, breastmilk, or milk in the baby bottle, via an oral syringe, or by spoon in one sitting. If you have any questions, check with your healthcare provider for how much and how often to give tecovirimat to your child.
AMOUNT OF THE FINAL DRUG-FOOD MIXTURE TO GIVE EACH DAY
Use the table below to find how much of the drug-food mixture to give to your child 2 times a day for 14 days, unless your doctor tells you otherwise.

<table>
<thead>
<tr>
<th>A Child’s weight in pounds*</th>
<th>B Dose</th>
<th>C Number of tecovirimat capsules needed to prepare the dose</th>
<th>D Amount of food or liquid to add</th>
<th>E How much of the drug-food mixture to give your child</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 13 pounds</td>
<td>¼ capsule (50 mg)</td>
<td>1</td>
<td>2 tablespoons (30 mL) of food or liquid</td>
<td>Thoroughly mix the capsule contents with food/liquid. Ensure the mixture is uniform. Give ¼ portion of the prepared mixture within 30 minutes of preparation. Throw out the remaining mixture. Give this amount 2 times each day.</td>
</tr>
<tr>
<td>13 to under 28 pounds</td>
<td>½ capsule (100 mg)</td>
<td>1</td>
<td>2 tablespoons (30 mL) of food or liquid</td>
<td>Thoroughly mix the capsule contents with food/liquid. Ensure the mixture is uniform. Give ½ portion of the prepared mixture within 30 minutes of preparation. Throw out the remaining mixture. Give this amount 2 times each day.</td>
</tr>
<tr>
<td>28 to under 55 pounds</td>
<td>1 capsule (200 mg)</td>
<td>1</td>
<td>2 tablespoons (30 mL) of food or liquid</td>
<td>Mix the capsule contents with food/liquid. Give the entire prepared mixture within 30 minutes of preparation. Give this amount 2 times each day.</td>
</tr>
<tr>
<td>55 to under 88 pounds</td>
<td>2 capsules (400 mg)</td>
<td>2</td>
<td>2 tablespoons (30 mL) of food or liquid</td>
<td>Mix the capsule contents with food/liquid. Give the entire prepared mixture within 30 minutes of preparation. Give this amount 2 times each day.</td>
</tr>
<tr>
<td>88 to under 264 pounds</td>
<td>3 capsules (600 mg)</td>
<td>3</td>
<td>2 tablespoons (30 mL) of food or liquid</td>
<td>Mix the capsule contents with food/liquid. Give the entire prepared mixture within 30 minutes of preparation. Give this amount 2 times each day.</td>
</tr>
<tr>
<td>264 pounds and above</td>
<td>3 capsules (600 mg)</td>
<td>3</td>
<td>2 tablespoons (30 mL) of food or liquid</td>
<td>Mix the capsule contents with food/liquid. Give the entire prepared mixture within 30 minutes of preparation. Give this amount 3 times each day.</td>
</tr>
</tbody>
</table>

*Adult dose is 3 capsules (600 mg). Follow the same instructions for opening 3 capsules and mixing with food. Individuals who weigh 264 pounds or more should take 3 capsules (600 mg) 3 times a day.

Storing or Leftover Final Drug-Food Mixture
- Use the final drug-food mixture within 30 minutes of preparation.
- Throw out any unused final drug-food mixture (make a new final drug-food mixture for each dose).