

Attachment 3: Instructions for Opening and Mixing Tecovirimat Capsules with Water or 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 water or food to give a drug-water or drug-food mixture. This sheet explains how to open the capsules and mix with water, milk, chocolate 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. See the table below to locate the dose for your child and follow the corresponding instructions. Children who weigh 88 pounds (40 kg) or more will 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 oral syringe that measures in milliliters (mL) or a tablespoon
- 1 dosing cup of suitable size or a small bowl
- One of these foods/liquids: water, milk, chocolate milk, baby food, apple sauce, yogurt, pudding, or chocolate syrup



DIRECTIONS FOR MAKING THE DRUG-WATER OR 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 dosing cup of suitable size or bowl. Carefully pull the capsule open and pour out the contents (white powder) completely into the dosing cup/bowl. Look inside the capsule to make sure no powder is left inside the capsule. Repeat for additional capsules, if applicable.

Step 4:

- **If making a dose for a child that weighs less than 28 pounds (13 kg):** Add 20 mL of water into the dosing cup containing the drug powder. Thoroughly mix by swirling the cup for at least 30 seconds until there are no clumps. Do not use a spoon or any other utensil to mix. This makes the water and drug mixture.
- **If making a dose for a child that weighs 28 pounds (13 kg) or more:** Add 2 tablespoons (30 mL) of liquid (e.g., milk, chocolate milk) or soft food (e.g., apple sauce, yogurt) into the dosing cup/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. If you have any questions, check with your healthcare provider for how much and how often to give tecovirimat to your child.

DISCARD LEFTOVER FINAL DRUG WATER OR DRUG-FOOD MIXTURE

- Use the final drug-water or drug-food mixture within 30 minutes of preparation.
- Throw out any unused final drug-water or drug-food mixture (make a new final drug-water or drug-food mixture for each dose).

• **AMOUNT OF THE FINAL DRUG-WATER OR DRUG-FOOD MIXTURE TO GIVE EACH DAY**

• Use the table below to find how much of the drug-water or drug-food mixture to give for 14 days unless your doctor tells you otherwise.

A	B	C	D	E
Weight in pounds (weight in kg)	Dose	Number of tecovirimat capsules needed to prepare the dose ^b	Amount of water ^c or food/liquid to add	How to prepare the drug-water or drug-food mixture and the amount to give or take Note: For a child weighing less than 28 pounds (13 kg), dosing should be followed by a feeding.
Under 7 pounds ^a (3 kg)	33.3 mg every 12 hours	1 	20 mL water	Carefully open 1 capsule and empty the entire contents into a dosing cup of suitable size. Add 20mL of water to the dosing cup and thoroughly mix by swirling the cup for at least 30 seconds until there are no clumps. Do not use a spoon or any other utensil to mix. Immediately after mixing, use an oral syringe to draw up and administer 3.3 mL of the water and drug mixture. Discard the remaining mixture. Give this amount 2 times each day, making a new mixture for each dose.
7 pounds to under 13 pounds ^a (3 kg to < 6 kg)	50 mg every 12 hours	1 	20 mL water	Carefully open 1 capsule and empty the entire contents into a dosing cup of suitable size. Add 20mL of water to the dosing cup and thoroughly mix by swirling the cup for at least 30 seconds until there are no clumps. Do not use a spoon or any other utensil to mix. Immediately after mixing, use an oral syringe to draw up and administer 5 mL of the water and drug mixture. Discard the remaining mixture. Give this amount 2 times each day, making a new mixture for each dose.
13 pounds to under 28 pounds ^a (6 kg to < 13 kg)	100 mg every 12 hours	1 	20 mL water	Carefully open 1 capsule and empty the entire contents into a dosing cup of suitable size. Add 20mL of water to the dosing cup and thoroughly mix by swirling the cup for at least 30 seconds until there are no clumps. Do not use a spoon or any other utensil to mix. Immediately after mixing, use an oral syringe to draw up and administer 10 mL of the water and drug mixture, either directly or mixed in a small amount of soft food (e.g., apple sauce, yogurt). Discard the remaining mixture. Give this amount 2 times each day, making a new mixture for each dose.
28 pounds to under 55 pounds (13kg to < 25 kg)	200 mg (1 capsule) every 12 hours	1 	2 tablespoons (30 mL) of food or liquid	Carefully open 1 capsule and mix the capsule contents with 30 mL of liquid (e.g., milk, chocolate milk, water) or soft food (e.g., apple sauce, yogurt). Administer the entire mixture within 30 minutes of preparation. Give this amount 2 times each day after a full meal containing moderate to high fat.
55 pounds to under 88 pounds (25 kg to < 40 kg)	400 mg (2 capsules) every 12 hours	2 	2 tablespoons (30 mL) of food or liquid	Carefully open 2 capsules and mix the capsule contents with 30 mL of liquid (e.g., milk, chocolate milk, water) or soft food (e.g., apple sauce, yogurt). Administer the entire mixture within 30 minutes of preparation. Give this amount 2 times each day after a full meal containing moderate to high fat.
88 pounds to under 264 pounds (40 kg to < 120 kg)	600 mg (3 capsules) every 12 hours	3 	2 tablespoons (30 mL) of food or liquid	Carefully open 3 capsules and mix the capsule contents with 30 mL of liquid (e.g., milk, chocolate milk, water) or soft food (e.g., apple sauce, yogurt). Administer the entire mixture within 30 minutes of preparation. Give this amount 2 times each day after a full meal containing moderate to high fat.
264 pounds and above (> 120 kg)	600 mg (3 capsules) every 8 hours	3 	2 tablespoons (30 mL) of food or liquid	Carefully open 3 capsules and mix the capsule contents with 30 mL of liquid (e.g., milk, chocolate milk, water) or soft food (e.g., apple sauce, yogurt). Administer the entire mixture within 30 minutes of preparation. Give this amount 2 times each day after a full meal containing moderate to high fat.

^a Do not administer dose without first mixing with water/soft food as outlined above.

^b Opening tecovirimat capsules and mixing in water for children weighing < 13 kg, which differs from the FDA-approved [tecovirimat package insert](#), is allowed under this IND protocol.

^c Use of water for oral dose preparation and administration is not in the FDA-approved labeling but is allowed under this IND protocol.