

Tecovirimat to Treat Smallpox and Smallpox Vaccine Complications during an Emergency

Emergency Use Instructions for Recipients

During a smallpox emergency, you will be given a medicine called tecovirimat (also called TPOXX®) because you may have smallpox or smallpox vaccine complications. Taking tecovirimat may reduce your chance of becoming very sick and dying from smallpox. If you have more questions about taking tecovirimat, ask a doctor or public health official.

What is smallpox?

Smallpox is a serious infectious disease caused by the **variola** virus that can kill about 3 out of 10 people who get it. People with smallpox have a distinctive and progressive rash with high fevers and head and body aches. For survivors it can cause significant and long-lasting complications such as severe scarring and blindness after the rash has healed. Smallpox is spread by humans primarily through direct, fairly prolonged face-to-face contact between people but can also be spread through contaminated objects such as bedding or clothing.

Before the smallpox vaccine was developed in 1796, smallpox used to kill millions of people worldwide. As a result of the vaccine, smallpox was declared eradicated from the world in 1980. Some people who get the smallpox vaccine (containing live vaccinia virus such as ACAM2000®) or come in contact with a person who got the vaccine may have serious reactions (such as a rash or eye infection). These reactions may happen when someone touches the vaccination site and then touches another part of their body or another person. These reactions require medical attention.



What are the symptoms of smallpox?

Smallpox can cause these symptoms:

- high fever
- vomiting
- red spots or sores on the tongue and mouth
- tiredness
- severe headaches and body aches
- severe rash or bumps on the skin

People usually experience fever and body aches first. Then red spots appear on the tongue and mouth, followed by a rash on the skin. At first, the rash appears as raised bumps that turn into pus-filled blisters. The blisters crust over, form scabs, and fall off after about 3 weeks.

What is tecovirimat?

Tecovirimat is a medicine that is approved by the Food and Drug Administration (FDA) to treat smallpox. It can also be used to treat smallpox vaccine complications. Tecovirimat works by stopping virus from spreading inside your body. This may help you to get better faster and reduce your risk of serious complications or death. Also, some bottles of tecovirimat may be labeled as ‘investigational’ because the product was labeled before FDA approval. If you are given tecovirimat that has an expired date, please note that FDA is allowing the use of certain lots of expired tecovirimat beyond the expiration date on the container based on FDA’s scientific review. For more information, go to the FDA website at www.fda.gov (search for “tecovirimat expiration”).

How do I take tecovirimat?

Adults 18 years of age or older and children weighing over 88 pounds (40 kg):

- Take three 200 mg capsules (a total of 600 mg) in the **morning** with a full glass of water after eating a full meal
- Take three 200 mg capsules (a total of 600 mg) in the **evening** with a full glass of water after eating a full meal

Children weighing 88 pounds (40 kg) or less:

- Take the number of pills as instructed by your healthcare provider in the **morning** and in the **evening** (every 12 hours) after eating a full, age appropriate meal
- Examples of meals include: egg, bacon, and cheese sandwich; bagel with cream cheese; hamburger; chicken with rice or potato; beans and rice with cheese; grilled cheese sandwich; nutritional supplement drink; etc.
- **If you or your child cannot swallow pills**, follow the instructions in [How to Prepare Tecovirimat with Liquid or Soft Food for Those Who Cannot Swallow Capsules](#).
- Keep tecovirimat capsules at room temperature (59–86°F) out of reach of children and pets. Call the poison control center if children or pets consume the medicine by accident (1-800-222-1222).

For how long do I take tecovirimat?

You should take tecovirimat for 14 days. Your doctor may instruct you to take the medicine for longer than 14 days depending on your symptoms.

What should I tell my healthcare provider before receiving tecovirimat?

Talk to your healthcare provider about any medications you are taking, including vitamins or supplements, and let them know of any questions you have. Tell your healthcare provider if you:

- are pregnant or plan to become pregnant
- are breastfeeding
- have diabetes or are taking blood sugar lowering medications, such as repaglinide (Prandin®)

What are the common side effects of tecovirimat?

The most common side effects of tecovirimat in healthy adults are:

- Headache
- Nausea
- Stomach pain
- Vomiting

What are the possible serious side effects of tecovirimat?

Low blood sugar can happen when tecovirimat is taken with blood sugar-lowering medications such as repaglinide (Prandin®). Tell your healthcare provider if you get any of the following symptoms of low blood sugar:

- Headache
- Drowsiness
- Hunger
- Feeling jittery or shaky
- Dizziness
- Confusion
- Sweating
- Weakness
- Fast heartbeat
- Irritability

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider.

What other treatment choices are there?

There are no other FDA-approved treatments for smallpox disease. There is an FDA-approved smallpox vaccine that can **help to prevent** people from developing smallpox disease. Smallpox vaccine cannot treat smallpox disease once you have it. Vaccinia Immune Globulin Intravenous (VIGIV) is approved by FDA for treatment of complications from smallpox vaccine, but is not approved to treat smallpox disease.

What if I decide not to take tecovirimat?

It is your choice whether or not to take tecovirimat. Smallpox disease can be serious and lead to long-term complications such as blindness or cause death. If you choose not to take tecovirimat, you may develop severe disease or could even die from smallpox. Even if you take tecovirimat, there is still a chance that you may get sicker or could die if the illness is severe.

What if I am pregnant or breastfeeding?

Smallpox disease during pregnancy can cause serious harm to the mother and the unborn baby. Tecovirimat has not been studied in pregnant or breastfeeding women. It is not known if giving tecovirimat to a pregnant woman could hurt her unborn child. Tecovirimat has been tested on pregnant mice, lactating mice, and rabbits at high doses and no serious problems in the unborn animals were found. The potential benefits of tecovirimat may outweigh the potential risks. If you are pregnant, discuss your treatment options and specific situation with your doctor.

How do I report side effects of tecovirimat or medication errors?

Tell your doctor or healthcare provider right away of any side effects or medication errors and report the side effect or error to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427 (toll-free).

How do I learn more?

If you have questions, please contact the CDC via telephone at 1-800-232-4630 (1-800-CDC-INFO) or visit CDC's website at www.cdc.gov.

Space Reserved for State/Local Public Health Information

How To Prepare Tecovirimat with Liquid or Soft Food for Those Who Cannot Swallow Capsules

PLEASE READ THESE INSTRUCTIONS AND CAREFULLY FOLLOW STEP 1 THROUGH STEP 6 BELOW:

This sheet explains how to open tecovirimat capsules and mix the powder from inside the capsules with food. It is important that you take tecovirimat (also called TPOXX[®]) every 12 hours (once in the morning AND once at night) each day for 14 days, or as directed by your healthcare provider.

Step 1: Gather the following supplies

- Bottle of **tecovirimat capsules**
- **Soft food or liquid** like baby food, applesauce, yogurt, pudding, milk, nutritional supplement, or juice.
- **Tablespoon or oral syringe** (1 tablespoon = 15 ml)
- **Small bowl**



Step 2: Measure out 2 tablespoons of food or liquid

- If your child is unable to eat soft foods, use a tablespoon or oral syringe to measure 2 tablespoons of liquid and add it into a bowl.
- If your child eats solid or soft foods, measure 2 tablespoons of the food and add it into a bowl.

Step 3: Use **Table 1** to look up how many capsules you need.

- Find the person's weight in **Column A** (or age in Column B if weight is unknown) and locate the number of capsules needed in **Column D**. Remove that number of capsules from the bottle. One (1) capsule contains 200 mg of drug.

Step 4: Open the capsules and pour the white powder from inside the capsule into the bowl with the food or liquid

- Twist open the capsule(s) by carefully twisting the ends of the capsule in opposite directions while gently pulling apart. Pour all the powder into the bowl with the food or liquid.
- You may need to tap the capsule to make sure all of the powder is out of the capsule.
- Throw out the empty capsule shells.

Step 5: Mix the powder and food/liquid together

- Gently stir the mixture with a spoon (up to 2 minutes). The powder will not completely dissolve but any clumps should be smoothed out using a spoon.

Step 6: Give the correct amount of the drug-food mixture

- Use **Column E** from **Table 1** to find the correct amount of the drug-food mixture to give.
- Give this amount of the drug-food mixture every 12 hours (once in the morning AND once at night) each day for 14 days, or as directed by your healthcare provider.
- Be sure to give the drug-food mixture within 30 minutes of eating a hearty meal. Examples of meals include: egg, bacon, and cheese sandwich; bagel with cream cheese; hamburger; chicken with rice or potato; beans and rice with cheese; grilled cheese sandwich; nutritional supplement drink; etc. For adults, the meal should consist of about 600 calories and 25 grams of fat.




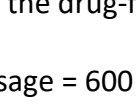
Leftover Drug-Food Mixture

- Use the drug-food mixture within 2 hours of preparing it.
- Throw any unused mixture away and keep out of reach from children and pets.
- Make a new drug-food mixture for each dose.

Remember to take tecovirimat **every 12 hours** (once in the morning AND once at night) **each day** for 14 days or as directed by your healthcare provider. Be sure that you **take tecovirimat with a hearty meal**.

How To Prepare Tecovirimat with Liquid or Soft Food for Those Who Cannot Swallow Capsules

TABLE 1. Doses of Tecovirimat to Mix with Food by Weight* (or Age)**

COLUMN A. Child's weight (lbs = pounds)	COLUMN B. Child's Age	COLUMN C. Amount of soft food/liquid	COLUMN D. # of tecovirimat capsules needed	COLUMN E. How much drug-food mixture to give my child every 12 hours (<u>once in the morning AND once at night</u>) each day
< 28 lbs	< 2 years	2 tablespoons (30 mL) of water	1 capsule 	<ul style="list-style-type: none"> • Measure out 1 tablespoon (15 mL) of the drug-water mixture and add it to about 1 tablespoon of infant formula or milk. • Mix well and give your child the entire amount of the mixed formula in one setting. • Throw away the remaining drug-water mixture. <p style="text-align: center;">Dosage = 100 mg (½ capsule)</p>
28 – 54 lbs	2 – 7 years	2 tablespoons (30 mL) of food or liquid	1 capsule 	<ul style="list-style-type: none"> • Give all of the drug-food mixture in one feeding. <p style="text-align: center;">Dosage = 200 mg (1 capsule)</p>
55 – 88 lbs	8 – 12 years	2 tablespoons (30 mL) of food or liquid	2 capsules 	<ul style="list-style-type: none"> • Give all of the drug-food mixture in one feeding. <p style="text-align: center;">Dosage = 400 mg (2 capsules)</p>
89 lbs or more	13 years or older	2 tablespoons (30 mL) of food or liquid	3 capsules 	<ul style="list-style-type: none"> • Give all of the drug-food mixture in one feeding. <p style="text-align: center;">Dosage = 600 mg (3 capsules)</p>

* The dose should be based on the person's weight (Column A). However, if the person's weight is unknown, age (Column B) can be used to determine the dose.

** Regardless of weight, the dose for **people 18 years of age and older** is 3 capsules (600 mg) every 12 hours (once in the morning AND once at night) for 14 days. Follow the same instructions for opening 3 capsules and mixing with food or liquid