

Tecovirimat 200 mg hard capsules (TPOXX®)

Information for the user

Background

Tecovirimat (TPOXX®) is used to treat viral infections, such as smallpox, monkeypox and cowpox (also known as orthopoxvirus disease) in adults and children weighing at least 13 kg. Tecovirimat is also used to treat complications from smallpox vaccines.

Tecovirimat works by stopping the virus from spreading. This will help your body to build up protection against the virus until you are better.

The **safety** of tecovirimat has been tested in humans between the ages of 18 and 79 years. As there are not many cases of orthopoxvirus disease in humans, the **effectiveness** of tecovirimat has so far only been studied in animals. These animal studies show that tecovirimat is effective in the treatment of orthopoxvirus diseases.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

1. How is tecovirimat taken?

A course of treatment lasts 14 days. It is important to finish the course even if you feel better. If you stop taking tecovirimat, your symptoms may return or become worse.

The recommended dose of tecovirimat for adults and children weighing 40 kg or more is:

- **three** tecovirimat 200 mg capsules (600 mg total dose) taken with food **every 12 hours**

The recommended dose of tecovirimat for children weighing 13 kg to less than 25 kg is:

- **one** tecovirimat 200 mg capsules taken with food **every 12 hours**

The recommended dose of tecovirimat for children weighing 25 kg to less than 40 kg is:

- **two** tecovirimat 200 mg capsules (400 mg total dose) taken with food **every 12 hours**

Tecovirimat should be taken within 30 minutes of eating a meal of moderate calories and fat content.

For individuals who are not able to swallow the capsules, your healthcare professional may recommend opening the hard capsule and mixing the contents with 30 mL of liquid (e.g., milk, chocolate milk) or soft food (e.g., apple sauce, yogurt).

- Wash and dry your hands before and after preparation
- Carefully open the capsule so that the contents do not spill or escape into the air
- Hold the capsule with the cap facing up and pull the cap away from the body of the capsule
- Use a small container for mixing
- Mix the entire contents of the capsule with 30 mL of liquid (e.g., milk, chocolate milk) or soft food (e.g., apple sauce, yogurt)
- If the recommended dose is for more than one capsule, repeat this process and mix the entire contents of each capsule into the liquid or soft food
- Give the mixture to the individual within 30 minutes after mixing and within 30 minutes of eating a meal
- Make sure the individual eats all of the mixture

If you take more tecovirimat than you should - let your healthcare professional know so that they can monitor you for any signs or symptoms of side effects.

If you forget to take or miss a dose of tecovirimat, skip that dose and continue with your next scheduled dose. Do not take a double dose to make up for a forgotten dose.

If you vomit within 30 minutes of taking tecovirimat, you may take another dose right away. If you vomit more than 30 minutes after taking tecovirimat, do not take another dose and continue with your next scheduled dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

2. Does tecovirimat have any side effects?

Like all medicines, tecovirimat can cause side effects, although not everybody gets them.

Headache is a very common side effect that may affect more than 1 in 10 people.

Dizziness, feeling or being sick, diarrhoea and abdominal pain are common side effects. They affect up to 1 in 10 people.

Uncommon side effects which may affect up to 1 in 100 people include:

- decreased appetite
- increased liver enzymes
- depression or anxiety
- irritability
- panic attacks
- migraine
- feeling tired or sleepy or unable to sleep
- being unable to concentrate or having a low attention span
- taste disturbances
- tingling or numbness in the hands, feet or mouth
- mouth pain
- constipation
- flatulence (wind)
- indigestion or upset stomach
- abdominal discomfort or swelling
- dry mouth
- dry or chapped lips
- mouth ulcers
- belching or burping
- heartburn
- itching or rash (hives)
- joint pain and stiffness
- fever
- chills
- generally feeling unwell (malaise)
- pain
- feeling thirsty
- abnormal electrical activity on brain scan readings
- lower numbers of red blood cells or white blood cells or platelets than usual in a blood test
- increased heart rate (tachycardia) or irregular heart rate

If you get any side effects, talk to your doctor, pharmacist or healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the [Yellow Card reporting site](#) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you are providing more information on the safety of this medicine.

3. Who may not be able to have tecovirimat?

Do not take tecovirimat if you are allergic to tecovirimat or any of the other ingredients of this medicine (listed in section 6)

Tecovirimat may not be suitable for everyone. Tell your healthcare professional if:

- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines)
- you have reduced function of your liver or kidneys
- you have epilepsy
- you are a child weighing less than 13 kg body weight

Do not drive or operate machines if you feel faint, dizzy, drowsy.

Tecovirimat contains lactose and sunset yellow (E110)

- if you have been told that you have an intolerance to some sugars, contact your healthcare professional before taking this medicine
- colouring agents such as sunset yellow (E110) may cause allergic reactions

4. Other medicines and tecovirimat

Speak to your healthcare professional if you are taking, have recently taken or might take any other medicines.

Taking tecovirimat with certain medicines may stop them from working properly, or make any side effects worse. Your healthcare professional may need to give you a different medicine or adjust the dose of medicine you are taking.

You must speak to your healthcare professional if you are taking any of the following medicines:

- repaglinide (used to treat blood sugar levels in diabetes)
- omeprazole, lansoprazole, or rabeprazole (used to treat ulcers or heart burn)
- midazolam (used to put people to sleep before a surgical procedure)
- bupropion (used to treat depression)
- atorvastatin (used to treat high cholesterol)
- flurbiprofen (used to treat pain)
- methadone (used to treat pain or withdrawal symptoms of narcotics)
- darunavir, maraviroc, or rilpivirine (used to treat HIV infection)
- sildenafil, tadalafil, or vardenafil (used to treat erectile dysfunction)
- voriconazole (used to treat fungal infections)
- tacrolimus (used to suppress the immune system)

5. Tecovirimat and pregnancy, breastfeeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before taking this medicine. Tecovirimat is not recommended during pregnancy, unless the benefits are considered to outweigh the risks.

It is not known whether tecovirimat is excreted in human milk. Breast-feeding is not recommended during treatment with this medicine. Tell your healthcare professional if you are breast-feeding or are planning to breast-feed before taking this medicine.

The effects of tecovirimat on fertility in humans have not been studied.

6. What tecovirimat looks like and contains

Tecovirimat are orange and black capsules, each printed with 'SIGA®' and 'ST-246' in white ink. The capsules are 21.7 mm long and 7.64 mm around the centre.

The active substance is tecovirimat monohydrate equivalent to 200 mg tecovirimat.

The other ingredients are:

- **Capsule core:** colloidal silicon dioxide, croscarmellose sodium (E468), hypromellose (E464), lactose monohydrate, magnesium stearate, cellulose, microcrystalline (E460) and sodium laurilsulfate (E487).
- **Capsule shell:** gelatin, brilliant blue FCF (E133), erythrosine (E127), sunset yellow (E110) and titanium dioxide (E171).
- **Printing ink:** shellac (E904), titanium dioxide (E171), isopropyl alcohol, ammonium hydroxide (E527), butyl alcohol, propylene glycol, and simeticone.

7. How to store tecovirimat

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Store below 25°C.

Do not use this medicine if you notice that the capsule is broken or damaged in any way.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Further information

Public Health Wales:

<https://phw.nhs.wales/topics/monkeypox/>



NHS 111 Wales:

<https://111.wales.nhs.uk/encyclopaedia/m/article/monkeypox>



Mae'r daflen hon hefyd ar gael yn Gymraeg. This leaflet is also available in Welsh.

