

Package leaflet: Information for the user

Tecovirimat SIGA 200 mg hard capsules tecovirimat

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tecovirimat SIGA is and what it is used for
2. What you need to know before you take Tecovirimat SIGA
3. How to take Tecovirimat SIGA
4. Possible side effects
5. How to store Tecovirimat SIGA
6. Contents of the pack and other information

1. What Tecovirimat SIGA is and what it is used for

Tecovirimat SIGA contains the active ingredient tecovirimat.

Tecovirimat SIGA is used to treat viral infections, such as smallpox, mpox and cowpox in adults and children weighing at least 13 kg.

Tecovirimat SIGA is also used to treat complications from smallpox vaccines.

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

2. What you need to know before you take Tecovirimat SIGA

The safety of Tecovirimat SIGA has been tested in humans between the ages of 18 and 79 years. Since there are not many cases of orthopoxvirus disease in humans, the effectiveness of tecovirimat has thus far only been studied in animals. Studies conducted in animals show that tecovirimat is effective in the treatment of orthopoxvirus diseases.

Do not take Tecovirimat SIGA

- If you are allergic to Tecovirimat SIGA or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Tecovirimat SIGA.

- 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).
- If you have reduced function of your liver or kidneys.
- If you have epilepsy.

Children and adolescents

This medicine should not be given to children less than 13 kg body weight.

Other medicines and Tecovirimat SIGA

Tell your doctor if you are taking, have recently taken or might take any other medicines. You must tell your doctor if you are taking any of the following medicines.

- repaglinide (a medicine used to treat blood sugar levels in diabetes)
- omeprazole, lansoprazole, or rabeprazole (used to treat ulcers or heart burn)
- midazolam (a medicine used to put people to sleep before a surgical procedure)
- bupropion (a medicine used to treat depression)
- atorvastatin (a medicine use to treat high cholesterol)
- flurbiprofen (a medicine used to treat pain)
- calcium acetate, lanthanum carbonate, sevelamer carbonate, or sucroferric oxyhydroxide (used to reduce high blood phosphate levels)
- methadone (a medicine 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 (a medicine used to treat fungus infections)
- tacrolimus (a medicine used to suppress the immune system)

Taking Tecovirimat SIGA with any of these may stop your medicines from working properly, or make any side effects worse. Your doctor may need to give you a different medicine or adjust the dose of medicine you are taking. The above is not a complete list of medicines that your doctor may need to alter.

Pregnancy and breast-feeding

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

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

Driving and using machines

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

Tecovirimat SIGA contains Lactose and sunset yellow (E110)

- Tecovirimat SIGA contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine also contains sunset yellow (E110), a colouring agent. This may cause allergic reactions.

3. How to take Tecovirimat SIGA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing at least 120 kg

The recommended dose is 600 mg (three tecovirimat 200 mg hard capsules) every 8 hours with food for 14 days.

Adults and children weighing between 40 kg and 120 kg

The recommended dose is 600 mg (three tecovirimat 200 mg hard capsules) every 12 hours with food for 14 days.

Children and adolescents weighing at least 13 kg

The recommended dose in children weighing at least 13 kg and less than 40 kg is described in the table below. Your doctor or pharmacist will advise you of the correct dose to give your child based on their weight.

Body Weight	Dose
13 kg to less than 25 kg	One Tecovirimat SIGA 200 mg capsule every 12 hours for 14 days (200 mg two times a day)
25 kg to less than 40 kg	Two Tecovirimat SIGA 200 mg capsules every 12 hours for 14 days (400 mg two times a day)

Method of administration

Take Tecovirimat SIGA within 30 minutes after eating a full meal of at least 600 calories. The meal should contain at least 25 grams of fat. This can be achieved with many common foods (e.g., 2 big handfuls of nuts, 2 tablespoons of oil, or 1.5 tablespoons of butter). This is very important to ensure that a sufficient amount of the medicine is taken up by your body. Swallow the capsules whole with 150ml to 200ml of water.

Adults and children who have difficulty swallowing capsules

For patients who are not able to swallow the capsules, the doctor 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). Give the mixture to the patient within 30 minutes after mixing and within 30 minutes of eating a meal. Make sure the patient eats all of the mixture.

The recommended paediatric and adult dosage and preparation instructions are given in the table below.

Body weight	Tecovirimat dose	Amount of liquid or soft food	Number of capsules	Food and tecovirimat mixture instructions
13 kg to less than 25 kg	200 mg	2 tablespoons	1 Tecovirimat capsule	Mix entire contents of 1 Tecovirimat capsule with 2 tablespoons of liquid or soft food.
25 kg to less than 40 kg	400 mg	2 tablespoons	2 Tecovirimat capsules	Mix entire contents of 2 Tecovirimat capsules with 2 tablespoons of liquid or soft food.
40 kg to less than 120 kg	600 mg	2 tablespoons	3 Tecovirimat capsules	Mix entire contents of 3 Tecovirimat capsules with 2 tablespoons of liquid or soft food.

120 kg and above	600 mg	2 tablespoons	3 Tecovirimat capsules	Mix entire contents of 3 Tecovirimat capsules with 2 tablespoons of liquid or soft food.
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If you take more Tecovirimat SIGA than you should

Let your doctor know if you take too many Tecovirimat SIGA capsules so that your doctor can monitor you for any signs or symptoms of side effects.

If you forget to take Tecovirimat SIGA

If you miss a dose, 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 stop taking Tecovirimat SIGA, your symptoms may return or become worse

Do not stop taking Tecovirimat SIGA before you have completed the course, or without talking to your doctor or pharmacist first.

If you vomit after taking Tecovirimat SIGA

If you vomit within 30 minutes of taking Tecovirimat SIGA, you may take another dose right away. If you vomit more than 30 minutes after taking Tecovirimat SIGA, 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.

4. Possible side effects

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

If you experience any of the following side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Very common side effects (may affect more than 1 in 10 people)

- Headache

Common side effects (may affect up to 1 in 10 people)

- Dizziness
- Feeling sick (nausea) or vomiting
- Diarrhoea
- Abdominal pain

Uncommon side effects (may affect up to 1 in 100 people)

- Decreased appetite
- Increased liver enzymes
- Depression or anxiety
- Irritability
- Depression
- 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 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
- If you have a scan of your brain's electrical activity called an electroencephalogram, it may show abnormal readings of electrical activity of the brain.
- If you have a blood test, it may show that you have lower numbers of red blood cells or white blood cells or platelets than usual.
- Increased heart rate (tachycardia) or irregular heart rate

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tecovirimat SIGA

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.

6. Contents of the pack and other information

What Tecovirimat SIGA contains

- The active substance is tecovirimat monohydrate equivalent to 200 mg tecovirimat
- The other ingredients are:
Capsule core: silica, colloidal anhydrous, 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.

What Tecovirimat SIGA looks like and contents of the pack

- Tecovirimat SIGA are orange and black capsules, each printed with ‘SIGA®’ and ‘ST-246’ in white ink. The capsules are 21.7 millimeters long and 7.64 millimeters around the centre.
- Tecovirimat SIGA is available in a pack containing 84 (2 bottles of 42) capsules.

Marketing Authorisation Holder

SIGA Technologies Netherlands B.V.
Prinsenhil 29,
Breda 4825 AX,
The Netherlands

Manufacturer

Millmount Healthcare Limited
Block-7, City North Business Campus,
Stamullen
Co. Meath
K32 YD60
Ireland

This leaflet was last revised in 11/2025

This medicine has been authorised under ‘exceptional circumstances’. This means that for ethical reasons it has been impossible to get complete information on this medicine.
See Section 2 – The benefits of tecovirimat have thus far only been shown in animal studies.