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Tecovirimat SIGA (*tecovirimat*)

An overview of Tecovirimat SIGA and why it is authorised in the EU

What is Tecovirimat SIGA and what is it used for?

Tecovirimat SIGA is a medicine to treat smallpox, monkeypox and cowpox, three infections caused by viruses belonging to the same family (orthopoxviruses). It is also used to treat complications that can happen following vaccination against smallpox. Tecovirimat SIGA is used in adults and children weighing at least 13 kg.

It contains the active substance tecovirimat.

How is Tecovirimat SIGA used?

The medicine can only be obtained with a prescription.

Tecovirimat SIGA is available as capsules to be taken by mouth, and the dose depends on bodyweight. Tecovirimat treatment should be initiated as soon as possible after diagnosis.

For more information about using Tecovirimat SIGA, see the package leaflet or contact your doctor or pharmacist.

How does Tecovirimat SIGA work?

Tecovirimat SIGA works by interfering with a protein called VP37 that is found on the surface of orthopoxviruses, including smallpox, monkeypox and cowpox. By interacting with this protein, the medicine prevents the viruses from reproducing normally, slowing down the spread of infection.

What benefits of Tecovirimat SIGA have been shown in studies?

Because smallpox, monkeypox and cowpox are either eradicated (smallpox) or occur sporadically in the EU, studies to assess the effectiveness of Tecovirimat SIGA in infected people could not be carried out.

The effectiveness of Tecovirimat SIGA was therefore evaluated based on studies in animals infected with lethal doses of orthopoxviruses, on studies on the medicine's effects in the human body, and on the way the medicine is absorbed, modified and removed from the body in humans and animals (pharmacodynamics and pharmacokinetics studies).

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Studies in animals who had received lethal doses of either monkeypox or rabbitpox viruses showed that treatment with Tecovirimat SIGA for 14 days significantly increased survival rates: when treatment started either 4 or 5 days after infection, between 80 and 100% of the animals that were treated with Tecovirimat SIGA survived. No animals in the placebo groups survived. The survival rate was 50% when treatment started 6 days after the infection.

The dose that is needed in humans to ensure that Tecovirimat SIGA will work as expected was determined based on comparative pharmacokinetics and pharmacodynamics studies carried out in animals and in humans.

What are the risks associated with Tecovirimat SIGA?

The most common side effects with Tecovirimat SIGA are headache (which may affect more than 1 in 10 people) and nausea (feeling sick) (which may affect up to 1 in 10 people).

For the full list of restrictions, see the package leaflet.

Why is Tecovirimat SIGA authorised in the EU?

The European Medicines Agency considered that Tecovirimat SIGA is effective at reducing mortality caused by smallpox, monkeypox and cowpox, based on animal studies. While the safety of the medicine was assessed in non-infected people, the side effects of Tecovirimat SIGA are expected to be similar in infected people and are considered acceptable. The European Medicines Agency therefore decided that Tecovirimat SIGA's benefits are greater than its risks and it can be authorised for use in the EU.

There are no other treatments authorised for the monkeypox and cowpox infections, which although rare can be fatal. In addition, while smallpox has been eradicated, this is an extremely serious infection, for which no treatment exists should an outbreak occur.

Tecovirimat SIGA has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about Tecovirimat SIGA due to the rarity of the diseases. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Tecovirimat SIGA?

Since Tecovirimat SIGA has been authorised under exceptional circumstances, the company that markets Tecovirimat SIGA will provide data on the effectiveness and safety of the medicine in patients given the medicine should an outbreak of smallpox occur.

What measures are being taken to ensure the safe and effective use of Tecovirimat SIGA?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tecovirimat SIGA have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tecovirimat SIGA are continuously monitored. Suspected side effects reported with Tecovirimat SIGA are carefully evaluated and any necessary action taken to protect patients.

Other information about Tecovirimat SIGA

Tecovirimat SIGA received a marketing authorisation valid throughout the EU on 06 January 2022.

Further information on Tecovirimat SIGA can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Tecovirimat-SIGA.

This overview was last updated in 01-2022.