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EMA recommends restricting use of Tecovirimat SIGA

The medicine was not effective for the treatment of mpox in randomised clinical trials

EMA's committee for human medicines, CHMP, has recommended that Tecovirimat SIGA should no longer be used for the treatment of mpox. This recommendation does not affect the other authorised uses of Tecovirimat SIGA, which include the treatment of smallpox, cowpox and complications from smallpox vaccines.

Mpox is a viral infection that typically starts with fever, swollen lymph nodes and muscle aches, followed by a painful rash with fluid-filled lesions. While most cases are mild and resolve without complications, mpox can lead to more serious illness in children, pregnant people and those with a weakened immune system.

The CHMP's recommendation for mpox follows a review of data from four studies carried out in different regions, which showed that treatment with Tecovirimat SIGA did not heal lesions faster compared with placebo (a dummy treatment) in people presenting with active mpox lesions (PALM007, STOMP, UNITY and PLATINUM-UK). The findings of these studies also showed that when compared with placebo, Tecovirimat SIGA did not improve other outcomes, such as relieving pain or helping to clear the virus from the body faster.

At the time of approval, it was not possible to carry out studies in infected people, as the viruses rarely circulated. Therefore, the approvals of Tecovirimat SIGA for mpox, as well as for smallpox, cowpox and complications from smallpox vaccines, were based on results from an animal model of mpox infection. The animal data demonstrated antiviral activity and a survival benefit when treatment was started early and a reduced efficacy if treatment was initiated later after exposure to the virus.

The abovementioned studies in human mpox were made possible due to subsequent disease outbreaks. While these did not demonstrate efficacy in mpox-infected patients with established skin lesions, the circumstances of use as well as clinical course could differ between poxvirus diseases. Therefore, clinical data on mpox may not be predictive of how animal model efficacy translates into clinical benefit for other diseases or other conditions of use for mpox. That is why the restriction is limited to the use of Tecovirimat SIGA for mpox treatment.

The CHMP also considered all other available data on the benefits and risks of Tecovirimat SIGA. These included data from programmes in the United States and Africa that give patients access to the medicine, as well as findings from an epidemiological study in the EU, animal studies, laboratory data

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showing how the medicine prevents the virus from spreading, information on how the medicine behaves in the body and other data from the published scientific research.

During the review, the CHMP consulted a group of experts in infectious diseases. The review was discussed by the Agency's Emergency Task Force in the context of its public health threats activities.

The review did not identify any new safety concerns associated with Tecovirimat SIGA.

There are no other medicines authorised in the EU for treating mpox infections. Patients who have already started treatment with Tecovirimat SIGA can complete their treatment course.

A letter including the above recommendations will be sent in due course to healthcare professionals prescribing, dispensing or administering the medicine.

Information for patients

- New patients should not initiate Tecovirimat SIGA for the treatment of mpox.
- This is because a review of all available data on the benefits and risks of Tecovirimat SIGA did not show any effect for the treatment of mpox in patients who had developed lesions on their skin and moist body surfaces (mucosa). Tecovirimat SIGA did not heal mpox lesions faster than placebo.
- Data from these studies also showed that Tecovirimat SIGA did not improve other outcomes such as relieving pain or clearing the virus from the body faster. Furthermore, the medicine was not shown to be effective in treating mpox caused by either clade I or clade II viruses.
- The review did not identify any new safety concerns with the medicine.
- Patients who have already started treatment with Tecovirimat SIGA can complete their treatment course.
- Once this recommendation is confirmed by the European Commission, Tecovirimat SIGA will no longer be authorised in the EU for the treatment of mpox.
- If you are taking Tecovirimat SIGA for the treatment of mpox, you should speak to your doctor about this decision and what it means for you and your treatment.

Information for healthcare professionals

- New patients should not initiate Tecovirimat SIGA for the treatment of mpox.
- This restriction follows a review of all available data on the medicine's benefits and risks, including available data from four randomised, placebo-controlled, double-blind clinical trials that evaluated the safety and efficacy of tecovirimat for the treatment of mpox.
- Of the four clinical trials, three were undertaken in the context of outbreaks related to Clade II mpox infections (STOMP, UNITY, PLATINUM-UK) while the fourth (PALM007) was conducted in the context of Clade I mpox in the Democratic Republic of Congo.
- Clade I viruses, found mainly in Central and East Africa, are associated with more severe disease, while clade II viruses, which were responsible for the outbreaks of mpox in the EU in 2022 and 2023, tend to cause milder illness.
- Of the four studies, final results were available from PALM007, whereas only primary analysis results were available from STOMP, and summary results were available from UNITY. PLATINUM-UK results were available in an unpublished manuscript.

- Tecovirimat failed to meet the primary endpoint of time to clinical resolution of mpox lesions compared with placebo in generally immunocompetent patients with active mpox lesions in all four trials under the conditions studied.
- Likewise, secondary endpoints across the respective trials, including pain reduction, as well as virologic outcomes, such as viral DNA, demonstrated no advantage for tecovirimat compared with placebo.
- In PALM007, mortality remained low and was comparable between treatment arms, precluding the detection of any mortality benefit with tecovirimat.
- In animal studies used to evaluate the efficacy of Tecovirimat SIGA at the time of authorisation, efficacy was demonstrated if treatment was initiated within four days after exposure to monkeypox or rabbitpox virus.
  - In non-human primates, initiating treatment later, 6 days after intravenous monkeypox viral challenge, resulted in a reduction of the survival rate compared to animals treated earlier (83% at 4 days, 50% at 6 days, 0% without treatment).
  - In the clinical trials, tecovirimat was administered on average 6-9 days after reported symptom onset when most patients had active mpox lesions.
  - While tecovirimat-treated patients did not achieve a faster time to lesion resolution versus placebo in these clinical trials, it is plausible that the patients were not treated early enough in their disease course for tecovirimat to be effective.
- No new safety concerns were identified in the review.
- There are no other medicines authorised in the EU for treating active mpox infections. Patients who have already started treatment with Tecovirimat SIGA can complete their treatment course.
- This recommendation does not affect the use of Tecovirimat SIGA for the treatment of smallpox, cowpox and complications from smallpox vaccines in adults and children with a body weight of at least 13 kg.
- Due to the lack of clinical data evaluating the efficacy of tecovirimat in treating these viruses in humans, the in vitro and animal data presented at the time of marketing authorisation are still considered relevant for the use of tecovirimat in treating smallpox, cowpox and complications from smallpox vaccines. Furthermore, the expected context of use and disease courses of smallpox, cowpox and complications from smallpox vaccines are each different compared to mpox. That is why the restriction is limited to the use of Tecovirimat SIGA in mpox.
- If this recommendation is confirmed by the European Commission, Tecovirimat SIGA will no longer be authorised in the EU for the treatment of mpox.

A direct healthcare professional communication (DHPC) will be sent to healthcare professionals prescribing, dispensing or administering the medicine. The DHPC will also be published on a dedicated page on the EMA website.

More about the medicine

Tecovirimat SIGA is an antiviral medicine that was authorised to treat smallpox, mpox 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 should be used as soon as possible after diagnosis, in accordance with the product information.

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

Tecovirimat SIGA was authorised under exceptional circumstances, a type of authorisation which is granted when a condition is rare or when gathering complete data in humans is not possible or would be unethical. As a condition of this authorisation, the company marketing Tecovirimat SIGA was required to provide yearly updates on the medicine's benefits and risks.

The World Health Organization (WHO) declared two public health emergencies of international concern (PHEICs) in response to mpox global outbreaks. As a result, several studies on the use of tecovirimat for the treatment of mpox have been conducted both within the EU and internationally. There was no public health emergency declared by the European Commission in Europe.

More about the procedure

The review of Tecovirimat SIGA has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.