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EMA starts review of Tecovirimat SIGA

Review follows concerns over effectiveness in treatment of mpox

EMA has started a review of Tecovirimat SIGA (tecovirimat) following emerging data from recent clinical trials suggesting a lack of effectiveness in the treatment of mpox (a disease caused by the monkeypox virus).

Preliminary results from two completed studies, PALM007 and STOMP, both sponsored by the United States' National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, suggested that patients with mpox who received Tecovirimat SIGA did not recover from skin lesions faster than those who received placebo (a dummy treatment). Preliminary results recently published from a third study, UNITY, also do not indicate faster skin lesions resolution compared to placebo in patients treated with tecovirimat.

Additional results and analyses from ongoing studies or recently completed ones[1,2,3] are still awaited and will also inform EMA's assessment.

Based on the information available so far, there are no new safety concerns precluding the use of the medicine. 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).

Tecovirimat SIGA was authorised in January 2022 to treat mpox, smallpox and cowpox in adults and children weighing at least 13 kg. Because mpox, smallpox and cowpox are either eradicated (smallpox) or occur sporadically in the EU, studies to assess whether Tecovirimat SIGA worked in infected people could not be carried out at the time of the initial authorisation. The medicine has therefore been authorised under 'exceptional circumstances' based on animal studies and 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). As a condition of the marketing authorisation, the company marketing Tecovirimat SIGA is required to provide an update annually on the medicine's benefits and risks.

[1] National Library of Medicine. 'Tecovirimat in non-hospitalized patients with monkeypox (PLATINUM-CAN)', clinicaltrial.gov, accessed 24 July 2025, https://clinicaltrials.gov/study/NCT05534165
[2] NHS Health Research Authority. 'Platinum trial' NHS Health Research Authority website, accessed 24 July 2025, https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/platinum-trial/
[3] National Library of Medicine. 'European trial into Mpox infection (EPOXI),' clinicaltrial.gov, accessed 24 July 2025, https://clinicaltrials.gov/study/NCT06156566

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

EMA's human medicines committee (CHMP) will now review all available data on the safety and effectiveness of Tecovirimat SIGA and make a recommendation on whether measures are necessary to ensure the safe and effective use of the medicine. EMA will communicate further once the review has concluded.

More about the medicine

Tecovirimat SIGA is an antiviral medicine used 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 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. By interacting with this protein, the medicine prevents the viruses from reproducing normally, slowing down the spread of infection.

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 (PALM007, STOMP and additional studies)[1,2,3]. There is 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 as new data became available in the 3rd annual re-assessment of Tecovirimat SIGA marketing authorisation under exceptional circumstances.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion.

The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.