11 November 2021
EMA/CHMP/606390/2021
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Tecovirimat SIGA

tecovirimat

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Tecovirimat SIGA, intended for the treatment of orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia complications).

The applicant for this medicinal product is SIGA Technologies Netherlands B.V.

Tecovirimat SIGA will be available as 200 mg hard capsules. The active substance of Tecovirimat SIGA is tecovirimat, a synthetic small antiviral molecule (ATC code: J05AX24) which inhibits the activity of the orthopoxvirus peripheral membrane protein (VP37), required for production of extracellular forms of virus.

The benefits of Tecovirimat SIGA in humans were predicted from studies showing that it improves survival in lethally challenged animals. The most common side effects are headache and nausea.

The full indication is:

> Tecovirimat SIGA is indicated for the treatment of the following viral infections in adults and children with body weight at least 13 kg:
>
> - Smallpox
> - Monkeypox
> - Cowpox

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

[2] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

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Tecovirimat SIGA is also indicated to treat complications due to replication of vaccinia virus following vaccination against smallpox, in adults and children with body weight at least 13 kg (see sections 4.4 and 5.1).

Tecovirimat SIGA should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.