11 November 2021
EMA/CHMP/505741/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Voraxaze

glucarpidase

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 Voraxaze[3], intended to reduce toxic plasma methotrexate concentration.

The applicant for this medicinal product is SERB SAS.

Voraxaze will be available as 1000 IU/ml powder for solution for injection. The active substance of Voraxaze is glucarpidase, a detoxifying agent for antineoplastic treatment (ATC code: V03AF09) that converts methotrexate to its inactive metabolites DAMPA and glutamate.

The benefits of Voraxaze are a clinically important reduction in methotrexate concentration in at least 62% of treated patients with a median reduction of > 98% in methotrexate concentration occurring within 15 minutes following glucarpidase administration, as observed in four compassionate-use, open-label multicentre studies. The most common side effects are burning sensation, headache, paraesthesia, flushing and feeling hot.

The full indication is:

> Voraxaze is indicated to reduce toxic plasma methotrexate concentration in adults and children (aged 28 days and older) with delayed methotrexate elimination or at risk of methotrexate toxicity.

Voraxaze is intended for use under medical supervision.

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.

[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.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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