10 November 2022
EMA/CHMP/855683/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sugammadex Amomed

sugammadex

On 10 November 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sugammadex Amomed, intended for the reversal of neuromuscular blockade induced by rocuronium in adults and children or vecuronium in adults.

The applicant for this medicinal product is AOP Orphan Pharmaceuticals GmbH.

Sugammadex Amomed will be available as a 100 mg/ml solution for injection. The active substance of Sugammadex Amomed is sugammadex, an antidote (ATC code: V03AB35). Sugammadex is a selective relaxant-binding agent which forms a complex with the muscle relaxants rocuronium and vecuronium, thereby reducing their ability to exert an effect. This results in the reversal of neuromuscular blockade and allows the muscles to resume normal function.

Sugammadex Amomed is a generic of Bridion, which has been authorised in the EU since 25 July 2008. Studies have demonstrated the satisfactory quality of Sugammadex Amomed. Since Sugammadex Amomed is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Bridion was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.
>
> For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.

Sugammadex Amomed should only be administered by, or under the supervision of an anaesthetist.

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

[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

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the European Commission.