16 September 2021
EMA/CHMP/493758/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sugammadex Mylan

sugammadex

On 16 September 2021, 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 Mylan, 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 Mylan Ireland Limited.

Sugammadex Mylan will be available as a 100 mg/ml solution for injection. The active substance of Sugammadex Mylan is sugammadex (ATC code: V03AB35). Sugammadex forms a complex with the neuromuscular blocking agents rocuronium or vecuronium in plasma, preventing them from binding to nicotinic receptors in the neuromuscular junction and thereby reversing neuromuscular blockade induced by rocuronium or vecuronium.

Sugammadex Mylan is a generic of Bridion, which has been authorised in the EU since 25 July 2008. Studies have demonstrated the satisfactory quality of Sugammadex Mylan. Since Sugammadex Mylan 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 Mylan 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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