



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2023
EMA/CHMP/178271/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Sugammadex Piramal

sugammadex

On 26 April 2023, 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 Piramal, intended to reverse the effects of the muscle relaxants rocuronium and vecuronium. The applicant for this medicinal product is Piramal Critical Care B.V.

Sugammadex Piramal will be available as a 100 mg/ml solution for injection. The active substance of Sugammadex Piramal 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 reversing their neuromuscular blockade effect and allowing muscles to function normally again.

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

