19 May 2022
EMA/CHMP/266795/2022
Committee for Medicinal Products for Human Use (CHMP)

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

# Sugammadex Fresenius Kabi

sugammadex

On 19 May 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 Fresenius Kabi, intended for reversal of neuromuscular blockade induced by rocuronium or vecuronium. The applicant for this medicinal product is Fresenius Kabi Deutschland GmbH.

Sugammadex Fresenius Kabi will be available as a 100 mg/ml solution for injection. The active substance of Sugammadex Fresenius Kabi 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 Fresenius Kabi is a generic of Bridion, which has been authorised in the EU since 25 July 2008. Studies have demonstrated the satisfactory quality of Sugammadex Fresenius Kabi. Since this medicine 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 Fresenius Kabi 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

[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

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

granted by the European Commission.