



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2024
EMA/CHMP/567626/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Bridion

sugammadex

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Bridion. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indication as follows:²

For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in **paediatric patients from birth to 17 years** ~~children and adolescents aged 2 to 17 years~~.

For information, the full indications for Bridion will be as follows:

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 paediatric patients from birth to 17 years.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to 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 New text in bold, removed text as strikethrough

