European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 30 May 2008
Doc.Ref. EMEA/CHMP/246405/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
BRIDION

International Nonproprietary Name (INN): ***sugammadex (as sodium salt)***

On 30 May 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Bridion 100 mg/ml, solution for injection intended for the reversal of neuromuscular blockade induced by rocuronium or vecuronium. The applicant for this medicinal product is N.V. Organon.

The active substance of Bridion is sugammadex, a modified gamma cyclodextrin, which is a Selective Relaxant Binding Agent (ATC code: V03AB35). It forms a complex with the neuromuscular blocking agents rocuronium or vecuronium in plasma and thereby reduces the amount of neuromuscular blocking agent available to bind to nicotinic receptors in the neuromuscular junction. This results in the reversal of neuromuscular blockade induced by rocuronium or vecuronium.

The benefit with Bridion is that it has been shown to be effective in the routine reversal of neuromuscular blockade induced by the non-depolarising neuromuscular blockers rocuronium and vecuronium and also in the immediate reversal of neuromuscular blockade induced by rocuronium. The most common side effect is dysgeusia (metal or bitter taste).

A pharmacovigilance plan for Bridion, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Reversal of neuromuscular blockade induced by rocuronium or vecuronium.” It is proposed that Bridion 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 (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Bridion and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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