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EPAR summary for the public

Bridion

sugammadex

This is a summary of the European public assessment report (EPAR) for Bridion. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Bridion.

What is Bridion?

Bridion is a solution for injection that contains the active substance sugammadex (100 mg/ml).

What is Bridion used for?

Bridion is used to reverse the effect of the muscle relaxants rocuronium and vecuronium. Muscle relaxants are medicines used during some types of operation to make the muscles relax, including the muscles that help the patient to breathe. Muscle relaxants make it easier for the surgeon to do the operation. Bridion is used to speed up the recovery from the muscle relaxant, usually at the end of the operation.

Bridion can be used in adults who have received rocuronium and vecuronium, and in children and adolescents who have received rocuronium.

The medicine can only be obtained with a prescription.

How is Bridion used?

Bridion can only be given by or under the supervision of an anaesthetist (a doctor specialised in anaesthesia). It is given as a single intravenous 'bolus' injection (given into a vein all at once). The standard dose of Bridion is between 2 and 4 mg per kilogram body weight, depending on how much the muscle relaxant is affecting the muscles.



A dose of 16 mg/kg can be used if rapid recovery from muscle relaxation is needed. This might be necessary if patients need to be able to start to breathe on their own again during the operation. This dose is expected to be used in only a limited number of the treatments (less than 1%).

In children and adolescents from two to 17 years of age, the recommended dose is 2 mg/kg body weight. Bridion is not recommended for use in children and adolescents for recovery after vecuronium, or for rapid recovery after any muscle relaxant.

How does Bridion work?

The active substance in Bridion, sugammadex, is a 'selective relaxant binding agent'. This means that it attaches to the muscle relaxants rocuronium and vecuronium forming a 'complex' that inactivates the muscle relaxants and stops them having an effect. As a result, the effect of blockade of the muscles due to rocuronium and vecuronium on the muscles is reversed, and the muscles begin to work normally again, including the muscles that help the patient to breathe.

How has Bridion been studied?

Bridion has been studied in four main studies in a total of 579 adults undergoing surgery using muscle relaxants.

Two of the studies, involving a total of 282 patients, looked at the effectiveness of 2 mg/kg Bridion in reversing moderate relaxation of the muscles due to rocuronium or vecuronium. Bridion was compared with neostigmine (another medicine used to stop the effect of muscle relaxants) given after rocuronium or vecuronium in the first study and after cis-atracurium (another muscle relaxant) in the second. The third study compared the effectiveness of 4 mg/kg Bridion with that of neostigmine after deep relaxation of the muscles using rocuronium or vecuronium in 182 patients.

The fourth study, involving 115 patients, looked at the effectiveness of 16 mg/kg Bridion in producing rapid reversal of the muscle relaxation using rocuronium. This was compared with spontaneous recovery after muscle relaxation using succinylcholine (another muscle relaxant).

An additional study looked at the effectiveness of Bridion given after rocuronium in 90 children and adolescents.

In all of the studies, the main measure of effectiveness was how long it took for the muscles to recover.

What benefit has Bridion shown during the studies?

Bridion was more effective than neostigmine in reducing the time it took for the muscles to recover, after both moderate and deep muscle relaxation using rocuronium or vecuronium.

After moderate muscle relaxation, the average time for recovery was between 1.4 and 2.1 minutes for 2 mg/kg Bridion, compared with 17.6 to 18.9 minutes for neostigmine. After deep muscle relaxation, recovery took an average of around 3.0 minutes with 4 mg/kg Bridion, compared with around 49.5 minutes for neostigmine.

When used for rapid recovery, patients receiving 16 mg/kg Bridion recovered after 4.2 minutes. In contrast, muscle relaxation recovered spontaneously after 7.1 minutes.

The effect of Bridion seen in adults was similar in adolescents and children aged over two years. There were too few children aged below two years to determine the safety and effectiveness of Bridion in this age group.

What is the risk associated with Bridion?

The most common side effects with Bridion (seen in between 1 and 10 patients in 100) are cough, airway problems due to the anaesthesia wearing off, reduced blood pressure and other complications such as changes in heart rate. For the full list of all side effects reported with Bridion, see the package leaflet.

Bridion must not be used in people who are hypersensitive (allergic) to sugammadex or any of the other ingredients.

Why has Bridion been approved?

The CHMP decided that Bridion's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Bridion?

A risk management plan has been developed to ensure that Bridion is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bridion, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Bridion

The European Commission granted a marketing authorisation valid throughout the European Union for Bridion on 25 July 2008.

The full EPAR for Bridion can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Bridion, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2015.