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# Bridion (*sugammadex*)

An overview of Bridion and why it is authorised in the EU

## What is Bridion and what is it used for?

Bridion is a medicine 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 from birth to 17 years of age who have received rocuronium.

Bridion contains the active substance sugammadex.

## How is Bridion used?

The medicine can only be obtained with a prescription and must be given by or under the supervision of an anaesthetist (a doctor specialised in anaesthesia). It is given as a single injection into a vein. The dose depends on the patient's age, weight and how much the muscle relaxant is affecting the muscles.

For more information about using Bridion, see the package leaflet or contact your doctor or pharmacist.

## 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 to form a complex that inactivates the muscle relaxants, blocking their effect. As a result, the muscle-relaxing effect of rocuronium and vecuronium is reversed and the muscles begin to work normally again, including the muscles that help the patient breathe.

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## What benefits of Bridion have been shown in studies?

Bridion has been studied in four main studies in a total of 579 adults undergoing surgery using muscle relaxants. In all the studies, the main measure of effectiveness was how long it took for the muscles to recover.

The studies found that Bridion was more effective than neostigmine (another medicine used to stop the effect of muscle relaxants) at reducing the time it took for the muscles to recover after both moderate and deep muscle relaxation using rocuronium or vecuronium.

Two of the studies, involving a total of 282 patients, compared the effect of Bridion with that of neostigmine given either after rocuronium or vecuronium or after cis-atracurium (another muscle relaxant). After moderate muscle relaxation, the average time until recovery was between 1.4 and 2.1 minutes with Bridion, compared with 17.6 to 18.9 minutes with neostigmine.

A third study involving 182 patients compared the effectiveness of Bridion with that of neostigmine after deep muscle relaxation using rocuronium or vecuronium. Recovery from deep muscle relaxation took an average of around 3 minutes with Bridion, compared with around 49.5 minutes for neostigmine.

A fourth study, involving 115 patients, looked at the effectiveness of Bridion at rapidly reversing muscle relaxation using rocuronium compared with spontaneous recovery after muscle relaxation using succinylcholine (another muscle relaxant). Patients who received Bridion recovered after 4.2 minutes compared with 7.1 minutes for patients with spontaneous recovery from muscle relaxation.

Two further studies looked at the effectiveness of Bridion given after rocuronium or vecuronium in children and adolescents. One study, which involved 288 children and adolescents (aged 2 to less than 17 years), found that the average time for recovery from moderate muscle relaxation was 1.6 minutes for those who received Bridion compared with 7.5 minutes for those who received neostigmine. The effect was consistent across the entire age range. For recovery from deep muscle relaxation, the average time was 2 minutes in children and adolescents who received Bridion, which is similar to the effect seen in adults.

A second study involved 145 children from birth up to 2 years old and compared the effect of Bridion with that of neostigmine in reversing muscle relaxation caused by rocuronium or vecuronium. Children given Bridion recovered from moderate muscle relaxation after an average of 1.4 minutes compared with 4.4 minutes for those given neostigmine. Recovery from deep muscle relaxation happened after an average of 1.1 minute in children given Bridion, which is similar to the effect seen in children aged 2 to 17 years and in adults.

## What are the risks associated with Bridion?

For the full list of side effects and restrictions with Bridion, see the package leaflet.

The most common side effects with Bridion (which may affect up to 1 in 10 people) include cough, airway problems due to the anaesthesia wearing off, other complications due to anaesthesia, reduced blood pressure and other complications due to the surgical procedure such as a change in heart rate.

## Why is Bridion authorised in the EU?

Bridion has been found to be effective at reversing the effect of the muscle relaxants rocuronium and vecuronium in adults; in children it has been shown to be effective at reversing the effect of rocuronium. The safety of Bridion is considered acceptable. The European Medicines Agency therefore decided that Bridion’s benefits are greater than its risks and that it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Bridion have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Bridion are continuously monitored. Suspected side effects reported with Bridion are carefully evaluated and any necessary action taken to protect patients.

## Other information about Bridion

Bridion received a marketing authorisation valid throughout the EU on 25 July 2008.

Further information on Bridion can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/bridion.

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