

BRIDION®

100 mg/mL

Sugammadex

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BRIDION.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given BRIDION against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, tell your doctor.

Keep this leaflet.

You may need to read it again.

What BRIDION is used for

BRIDION belongs to a group of medicines called Selective Relaxant Binding Agents. It is used to speed up recovery of your muscles after an operation.

During some operations, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation. To make your muscles relax, the general anaesthetic includes muscle relaxants such as rocuronium or vecuronium. Because the muscles needed for breathing also become relaxed, you will need help with your breathing (artificial ventilation) during and after your operation until you can breathe on your own again.

BRIDION is used to stop the muscle relaxants working. It does this by combining with rocuronium or vecuronium in your body.

BRIDION is given to speed up your recovery from the muscle relaxant - for example, at the end of an operation to allow you to breathe normally earlier.

Your doctor will have explained why you are being treated with BRIDION.

Ask your doctor if you want any more information about this medicine.

BRIDION is not addictive.

Before you are given BRIDION

You may already have been given BRIDION Injection. Your doctor will have considered the situation carefully and decided to use it.

When you must not be given it

You must not be given BRIDION if:

- you are allergic to sugammadex or have an allergy to any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the tongue and/or throat
- rash or red skin

Before you are given it

Tell your doctor if you have kidney disease or have had it in the past.

This is important because BRIDION is removed from your body by the kidneys.

Tell your doctor if you have any diseases known to give an increased risk of bleeding (disturbance of blood clotting).

Tell your doctor if you have liver disease or have had it in the past.

Tell your doctor if you have fluid retention (oedema).

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or might be pregnant or are breast-feeding.

Your doctor will discuss the risks and benefits of using BRIDION if you are pregnant or breast-feeding.

BRIDION is not recommended for infants less than 2 years of age.

If you have not told your doctor about any of the above, tell them before you are given BRIDION.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

BRIDION may affect other medicines or be affected by them.

Tell your doctor if you are taking or have recently taken:

- toremifene (used to treat breast cancer)
- fusidic acid (an antibiotic)
- flucloxacillin (an antibiotic)

These medicines can reduce the effect of BRIDION.

Tell your doctor if you are using a hormonal contraceptive such as the "PILL", vaginal ring, implants or hormonal Intrauterine System (IUS).

BRIDION can make hormonal contraceptives less effective because it reduces how much you get of the hormone progestogen. The amount of progestogen lost by using BRIDION is about the same as missing one oral contraceptive Pill.

If you are taking the PILL the same day as BRIDION is given to you, follow the instructions for a missed dose in the Pill's package insert.

If you are using OTHER hormonal contraceptives (such as a vaginal ring, implant or IUS), you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days.

Laboratory tests: In general, BRIDION does not have an effect on laboratory tests. However it may affect the results of a blood test for a hormone called progesterone.

How BRIDION is given

BRIDION is given as a single injection through an intravenous line.

The doctor will work out the dose of BRIDION you need based on:

- your weight
- how much muscle relaxant is still affecting you

The usual dose is 2 - 4 mg per kg body weight. A dose of 16 mg per kg can be used only in adults if urgent recovery from muscle relaxation is needed.

The dose of BRIDION for children and adolescents between 2-17 years old is 2 mg per kg.

Overdose

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much BRIDION. Even if this happens, it is unlikely to cause any problems.

After having BRIDION

Things to be careful of

Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery. As far as it is known, BRIDION has no effect on alertness or concentration.

Side effects

Like all medicines, BRIDION can cause side effects, but not everyone gets them.

If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.

- Cough.
- Airway difficulties that may include coughing or moving as if you are waking or taking a breath.
- Light anaesthesia - you may start to come out of deep sleep and need more anaesthetic. This might cause you to move or cough at the end of the operation.
- Complications during your procedure such as changes in heart rate, coughing or moving.
- Decreased blood pressure due to the procedure.
- Allergic reactions such as a rash or red skin, swelling of the tongue and/or throat, shortness

of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease in blood pressure. Severe allergic or allergic-like reactions can be life threatening. Allergic reactions were reported more commonly in healthy, conscious volunteers.

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems.
- Return of muscle relaxation after the operation.
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when Bridion is administered.

If after your operation, you notice any side effects tell your doctor.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Ask your doctor to answer any questions you may have.

Storage

BRIDION is stored in the hospital according to the storage conditions on the pack.

Product description

What it looks like

BRIDION is a colourless to slightly yellow solution for injection.

BRIDION is available as

- 200 mg/2 mL pack of 10 vials
- 500 mg/5 mL pack of 10 vials

Ingredients

It contains 200mg or 500mg sugammadex as the active ingredient.

It also contains hydrochloric acid and/or sodium hydroxide for pH adjustment and Water for Injections.

Distributor

In Australia :

Merck Sharp & Dohme (Australia)
Pty Limited
Level 1, Building A, 26 Talavera
Road,
Macquarie Park, NSW 2113

Australian Registration Numbers:
AUST R 147716 (200 mg)
AUST R 148263 (500mg)

In New Zealand :

Merck Sharp & Dohme (New
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