PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BRIDION® 100 mg/mL Solution for Injection

Sugammadex

Read all of this leaflet carefully before you are given BRIDION.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- BRIDION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BRIDION is and what it is used for
2. What you need to know before you are given BRIDION
3. How to use BRIDION
4. Possible side effects
5. How to store BRIDION
6. Contents of the pack and other information

1. What BRIDION is and what it is used for

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

BRIDION is given to speed up your recovery from the muscle relaxant which is part of the anaesthetic regimen to allow the surgeon to do the operation. BRIDION will be given to you at the end of an operation to allow you to breathe normally earlier.

2. What you need to know before you are given BRIDION

You should not be administered BRIDION

- if you are hypersensitive (allergic) to sugammadex sodium or any of the other ingredients of BRIDION.
- if you have severe kidney disease.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection

- if you have kidney disease or have had it in the past. This is important as BRIDION is removed from your body by the kidneys.
- if you have liver disease or have had it in the past.
- if you have fluid retention (oedema).
- if you are on a controlled salt diet.
- if you have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or anticoagulation medication.

Other medicines and BRIDION

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines reduce the effect of BRIDION

It is especially important that you tell your doctor or pharmacist if you have recently taken:

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

BRIDION can affect hormonal contraceptives.

BRIDION can make hormonal contraceptives including:

- the 'Pill'
- vaginal ring
- implants
- hormonal intrauterine contraceptive device (IUCD)

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

- If you are taking the **Pill** on 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 (for example a vaginal ring, implant or IUS) you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days.

Effects on blood tests

BRIDION does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone and some blood clotting tests.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, it is not advisable to receive BRIDION. Please consult your doctor for advice.

Driving and using machinery

There is no information to suggest that BRIDION affects the ability to drive or operate machinery.

3. How to receive BRIDION

BRIDION will be given to you by your doctor. It is given as a single injection through an intravenous line.

If you are given more BRIDION than you should

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much BRIDION.

If you have received too much BRIDION, your doctor will take appropriate corrective measures.

4. Possible side effects

BRIDION can have side effects. If these side effects occur while you are under anaesthesia, they will be seen and treated by your doctor.

Frequent side effects

- Cough.
- Airway difficulties that may include coughing or moving as if you are waking or taking a breath.

- A temporary unpleasant taste in your mouth.
- Light anaesthesia - you may start to come out of deep sleep, so 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 surgical procedure.

Less frequent side effects

- Allergic (hypersensitivity) reactions - such as a rash or red skin, swelling of your tongue and/or throat, changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure. Severe allergic or allergic-like reactions can be life-threatening. The doctor will attend to it.
- Being awake during the operation (anaesthesia awareness).
- 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.
- Your muscles may be weakened for longer than expected after operation.
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when BRIDION is administered.

Not all side effects reported for BRIDION are included in this leaflet. Should your general health worsen after your operation, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BRIDION.

5. How to store BRIDION

The hospital will keep BRIDION according to the correct storage conditions as listed below:

- Store at or below 30 °C.
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light. When not protected from light, the vial should be used within 5 days.
- After first opening and dilution, chemical and physical in-use stability has been demonstrated for 48 hours at 2 to 25 °C. From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.
- Keep all medicines out of reach and sight of children.
- All unused medicine should be returned to the pharmacist.
- Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What BRIDION contains

- The active substance is sugammadex.
- Each millilitre (mL) of solution for injection contains 100 mg of sugammadex.
- A 2 mL vial contains 200 mg sugammadex (as the sodium salt).
- The other ingredients are: water for injection, hydrochloric acid and/or sodium hydroxide.

What BRIDION looks like and contents of the pack

BRIDION is packed in colourless, glass vials, sealed with grey, chlorobutyl rubber stoppers firmly sealed with aluminium crimp-cap with polypropylene, “flush edge”, flip-off buttons. The rubber stoppers do not contain latex.

Pack sizes: 10 vials of 2 mL.

BRIDION 100 mg/mL is a clear and colourless to slightly yellow solution with pH of between 7 and 8.

Holder of certificate of registration

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