

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

BRIDION[®]
solution for injection,
100 mg/mL sugammadex (as sugammadex sodium)

Read this carefully. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BRIDION[®].

Serious Warnings and Precautions

- This drug should be administered only by trained healthcare providers familiar with the use, actions, characteristics, and complications of neuromuscular blocking agents (NMBA) and neuromuscular block reversal agents.
- This drug may cause allergic reactions. Severe allergic or allergic-like reactions can be life threatening.

What is BRIDION[®] used for?

BRIDION[®] is used to help speed up the recovery of your muscles after an operation in adults.

How does BRIDION[®] work?

When you have surgery you are given drugs that help your muscles relax completely. These types of drugs are known as muscle relaxants. Rocuronium and vecuronium are a type of muscle relaxant that the doctor may give to you before your surgery. When your muscles are relaxed it makes it easier for the doctor to do the surgery. At the end of your surgery, BRIDION[™] is given to help get rid of the effects of these muscles relaxants.

What are the ingredients in BRIDION[®] ?

Medicinal ingredients: sugammadex.

Non-medicinal ingredients: hydrochloric acid, sodium hydroxide, water for injection

BRIDION[®] comes in the following dosage forms:

Solution for Injection: 100 mg/mL

Do not use BRIDION[®] if you:

- are allergic to sugammadex or to any of the other ingredients in BRIDION[®]. Tell your doctor who will be giving you the anesthesia if you have any allergies. This includes any allergies to food or other drugs.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BRIDION[®]. Talk about any health conditions or problems you may have, including if you:

- have heart problems
- have liver disease or have had it in the past
- have fluid retention (edema)
- have kidney disease or have had it in the past or are on dialysis. This is important as BRIDION[®] is removed from your body by the kidneys. Tell your doctor who will be giving you the anesthesia if this applies to you.
- are pregnant or might be pregnant
- are breastfeeding
- have diseases which are known to give an increased risk of bleeding (trouble with blood clotting)
- have a history of airway or lung problems

Other warnings you should know about:

Driving and using machines: Your doctor will tell you when it is safe to drive or use machines after you have been given BRIDION[®]. BRIDION[®] is not expected to have an effect on alertness or concentration.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BRIDION[®]:

- toremifene (used to treat breast cancer)
- fusidic acid (used to treat infections)

It is important that you tell your doctor who will be giving you the anesthesia if you have recently taken these medicines.

BRIDION[®] can affect hormonal contraceptives used for birth control:

BRIDION[™] can make birth control methods less effective because it reduces how much you get of the hormone progestogen. Tell your doctor if you are currently using any of the following:

- the ‘Pill’
- vaginal ring
- implants
- hormonal Intra Uterine Device (IUD)

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.
- using other **non-oral** contraceptive methods (for example a vaginal ring, implant or IUD, you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days.

Effects on blood tests:

In general, BRIDION[®] does not have an effect on laboratory tests. However, it may change the results of a blood test for progesterone (a hormone).

How to take BRIDION[®]:

BRIDION[™] will be given to you by a doctor who is trained in giving drugs used when you are having surgery. It is given through your vein as a single injection.

Usual dose:

Your doctor will determine the dose of BRIDION[™] you need. It is based on your weight and how much the muscle relaxant drugs are still affecting you.

Usual dose: 2mg - 4 mg per kg of body weight. The doctor will determine exactly how much you will be given.

Overdose:

Your doctor will be monitoring you carefully. BRIDION[®] is for hospital use only.

Missed Dose:

Not applicable.

What are possible side effects from using BRIDION[®] ?

These are not all the possible side effects you may feel after you have been given BRIDION[®]. After your operation, if you experience any side effects that are not listed here or you notice any of your side effects getting worse, tell the doctor or nurse right away.

- Allergic reaction such as:
 - a rash or red skin
 - swelling of your tongue and/ or throat
 - shortness of breath
 - changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure.
 - severe allergic or allergic-like reactions (anaphylaxis) that can be life threatening.
- Slow heart rate that can be life threatening.
- Complications during your procedure such as:
 - airway difficulties
 - changes in heart rate
 - coughing or moving.
 - light anesthesia that needs the attention of your doctor.
- Decreased blood pressure during the surgical procedure
- Return of muscle relaxation after the operation
- Shortness of breath due to muscle spasm of the airways (bronchospasm or laryngospasm)

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The hospital will store BRIDION[®] according to the correct storage conditions.

If you want more information about BRIDION[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#) or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594

To report an adverse event related to BRIDION[®], please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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