

Consumer Medicine Information

# Sugammadex BNM

## *Sugammadex*

Solution for injection 100 mg/mL

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## What is in this leaflet

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Please read this leaflet carefully before you are given Sugammadex BNM.

This leaflet answers some common questions about Sugammadex BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from [www.medsafe.gov.nz](http://www.medsafe.gov.nz).

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you Sugammadex BNM against the benefits this medicine is expected to have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may want to read it again.

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## What Sugammadex BNM is used for

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Sugammadex BNM contains Sugammadex. It 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 and 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.

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

Sugammadex BNM 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 Sugammadex BNM

Your doctor may have prescribed this medicine for another reason.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

Sugammadex BNM is only available with a doctor's prescription.



Sugammadex BNM is not addictive.

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## **Before you are given Sugammadex BNM**

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Sugammadex BNM is not suitable for everyone.

You may already have been given Sugammadex BNM 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 Sugammadex BNM 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.

**Do not use it after the expiry date printed on the pack.**

If you are given this medicine after the expiry date has passed, it may not work as well.

**Do not use it if the packaging is torn or shows signs of tampering.**

### ***Before you are given it***

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

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

This is important because Sugammadex BNM 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 are pregnant or might be pregnant or are breast-feeding.**

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

**Sugammadex BNM 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 Sugammadex BNM.**



## ***Taking other medicines***

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

Sugammadex BNM 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 Sugammadex BNM.

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

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

If you are taking the PILL the same day as Sugammadex BNM 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, Sugammadex BNM does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone.

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## **How Sugammadex BNM is given**

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### ***How it is given***

Sugammadex BNM is given as an injection into your vein (intravenously) as a single injection.

### ***How much will be given***

The doctor will work out the dose of Sugammadex BNM 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 Sugammadex BNM for children and adolescents between 2-17 years old is 2 mg per kg.



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## In case of overdose

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

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## Side effects

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Like all medicines, Sugammadex BNM 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 Sugammadex BNM is administered.

**If after your operation, you notice any side effects tell your doctor.  
Ask your doctor to answer any questions you may have.**

**Tell your doctor if you notice anything else that is making you feel unwell.**  
Other side effects not listed above may also occur in some patients.

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## After having Sugammadex BNM

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### ***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, Sugammadex BNM has no effect on alertness or concentration.

### ***Storage***

Sugammadex BNM will be stored in the pharmacy or on the ward under the recommended storage conditions.



## ***Disposal***

Any Sugammadex BNM which has passed its expiry date, or is left in the container after use, will be disposed of in a safe manner by your doctor, nurse or pharmacist.

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## **Product description**

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### ***What it looks like***

Sugammadex BNM is a clear, colourless to slightly yellow/ brown sterile solution for injection.

It is available in glass vials of 2 mL or 5mL in pack size of 10 vials per carton.

### ***Ingredients***

#### Active ingredient:

- sugammadex sodium

#### Inactive ingredients:

- hydrochloric acid and/or sodium hydroxide
- water for injections

Sugammadex BNM does **not** contain lactose, sucrose, tartrazine or any other azo dyes.

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## **Sponsor details**

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## **Date of preparation**

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This leaflet was prepared on 12 August 2021.

