



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER  
**SUGAMMADEX INJECTION**  
Sugammadex sodium 100mg/ml

**Read this leaflet carefully before you start taking this medicine.**

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

**In this leaflet:**

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

**1. WHAT SUGAMMADEX IS AND WHAT IT IS USED FOR**  
**Sugammadex contains the active substance Sugammadex.**

Sugammadex Injection is used to speed up the recovery of your muscles after an operation to allow you to breathe on your own again earlier. Sugammadex Injection does this by combining with the rocuronium bromide or vecuronium bromide in your body. Sugammadex Injection can be used in adults whenever Rocuronium bromide or Vecuronium bromide is used and in children and adolescents (aged 2 to 17 years) when rocuronium bromide is used for a moderate level of relaxation.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE SUGAMMADEX INJECTION**

You must not be given Sugammadex:

- If you are allergic to Sugammadex or any of the other ingredients of this medicine. Tell your anaesthetist if this applies to you.

**Warnings and precautions**

Talk to your doctor or nurse before you are given Sugammadex:

- If you have kidney disease or had in the past. This is important as Sugammadex 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 have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or anticoagulation medication

**Please tell this situation to your Healthcare provider.**

If these warnings are valid for you, even at any time in the past, please consult your doctor.



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**Children and adolescents**

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

**Other medicines and Sugammadex Injection**

Sugammadex Injection may affect other medicines or be affected by them. Tell your anaesthetist if you are taking, have recently taken or might take any other medicine.

**Some medicines reduce the effect of Sugammadex Injection.**

It is especially important that you tell your anaesthetist if you have recently taken:

- Toremifene (used to treat breast cancer).
- Fusidic acid (an antibiotic).

**Sugammadex Injection can affect hormonal contraceptives.**

Sugammadex Injection can make hormonal contraceptives, including the 'Pill', vaginal ring, implants, or a hormonal IntraUterine System (IUS), less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using Sugammadex Injection is about the same as missing one oral contraceptive Pill.

- If you are taking the Pill on the same day as Sugammadex Injection is given to you, follow the instructions for a missed dose in the Pill's package leaflet.
- 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**

In general, Sugammadex Injection does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone. Consult your doctor if your progesterone levels need to be tested on the same day you receive Sugammadex Injection.

*If you are using or have recently used any prescribed or non-prescription drugs, please inform your physician or pharmacist.*

**Pregnancy and breast-feeding**

**Pregnancy**

Please consult your physician or pharmacist before taking the drug.

Tell your anaesthetist if you are pregnant or might be pregnant or if you are breast-feeding. You may still be given Sugammadex Injection, but you need to discuss it first. It is not known whether sugammadex can pass into breast milk. Your anaesthetist will help you decide whether to stop breast-feeding, or whether to abstain from sugammadex therapy, considering the benefit of breast-feeding to the baby and the benefit of Sugammadex Injection to the mother.



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If you realize that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

**Breast-Feeding**

- Please consult your physician or pharmacist before taking the drug.
- Tell your anaesthetist if you are breast-feeding.

**Driving and using heavy machines:**

This medicine may make you feel sleepy and affect the speed of your reactions. After you have been given this medicine, you should not drive or use tools or machines until the next day. In general, it is wise to ask your doctor whether it is safe to drive.

**3. HOW TO TAKE SUGAMMADEX INJECTION**

Sugammadex Injection will be given to you by your anaesthetist, or under the care of your anaesthetist.

Your anaesthetist will work out the dose of Sugammadex Injection you need based on your weight and how much the muscle relaxant medicine is still affecting you. The usual dose is 2-4 mg per kg body weight. A dose of 16 mg/kg can be used in adults if urgent recovery from muscle relaxation is needed.

Sugammadex Injection will be given as a single injection through an intravenous line to you by your anaesthetist.

The dose of Sugammadex Injection for children is 2 mg/kg (children and adolescents between 2-17 years old).

For the elderly, the same dose recommendation as for adults should be followed.

**Liver and renal impairment**

- For the patient with mild and moderate liver or renal impairment, the same dose recommendation as for adults should be followed.
- Sugammadex Injection should not be given to patients with severe renal impairment.
- If you are under the impression that the effect of Sugammadex Injection is too strong or weak, consult your physician or pharmacist.

**If too much of Sugammadex is given**

As your anaesthetist will be monitoring your condition carefully, it is unlikely that you will be given too much Sugammadex Injection. But even if this happens, it is unlikely to cause any problems.



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**4. POSSIBLE SIDE EFFECTS**

Like all medicines this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine (frequency not known).

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

The side effects are listed as shown in the following categories:

Side effects are listed as shown in the following categories:

- **Very common:** It can be seen in at least one of 10 patients.
- **Common:** Less than one in 10 patients, but more than one in 100 patients.
- **Uncommon:** Less than one in 100 patients, but more than one in 1,000 patients.
- **Rare:** Less than one in 1,000 patients, but more than one in 10,000 patients.
- **Very rare:** Less than one in 10,000 patients can be seen.
- **Unknown:** It cannot be estimated from the available data.

**Common side effects:**

- Cough
- Airway difficulties that may include coughing or moving as if you are waking or taking a breath.
- Light anesthesia - you may start to come out of deep sleep, so need more anesthesia. This might cause you to move or cough at the end of the operation.
- Complications during your operation such as changes in heart rate, coughing or moving.
- Decreased blood pressure due to the surgical procedure

**Uncommon side effects**

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems.
- Allergic (drug hypersensitivity) reactions - such as a rash, 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. Allergic reactions were reported more commonly in healthy, conscious volunteers.
- Return of muscle relaxation after the operation

**Unknown**

- Severe slowing of the heart as well as slowing of the heart up to cardiac arrest may occur when Sugammadex Injection is administered.

*If you notice an aggravation of any side effects after surgery, or if you experience a side effect that is not included in this list, tell your doctor or anesthesiologist immediately about this situation.*



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**5. HOW TO STORE SUGAMMADEX INJECTION**

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Sugammadex Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

**6. FURTHER INFORMATION.**

**What SUGAMMADEX INJECTION contains**

Each ml of Sugammadex Injection contains 100mg of Sugammadex.

**What SUGAMMADEX INJECTION looks like and contents of the pack**

Clear transparent liquid in 10x2ml glass ampoules packed in an inner carton.

**SUPPLIER AND MANUFACTURER**

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