Package leaflet: Information for the patient

Sugammadex 50 mg/ml solution for injection in pre-filled syringe
Sugammadex 10 mg/ml solution for injection in pre-filled syringe
sugammadex

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your anaesthesist or doctor.
- If you get any side effects, talk to your anaesthesist or other doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sugammadex is and what it is used for

What Sugammadex is
Sugammadex contains the active substance sugammadex.
Sugammadex is considered to be a *Selective Relaxant Binding Agent* since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

What Sugammadex is used for
When you have some types of operations, your muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic you are given includes medicines to make your muscles relax. These are called muscle relaxants, and examples include rocuronium bromide and vecuronium bromide. Because these medicines also make your breathing muscles relax, you need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again.
Sugammadex is used to speed up the recovery of your muscles after an operation to allow you to breathe on your own again earlier. It does this by combining with the rocuronium bromide or vecuronium bromide in your body.
It 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 Sugammadex is given

You should not be given Sugammadex
- if you are allergic to sugammadex or any of the other ingredients of this medicine (listed in section 6).

→ Tell your anaesthetist if this applies to you.

Warnings and precautions
Talk to your anaesthesist before Sugammadex is given
- 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.

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

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

Some medicines reduce the effect of Sugammadex
→ 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 can affect hormonal contraceptives
- Sugammadex can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal Intra Uterine System (IUS) - less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using Sugammadex is about the same as missing one oral contraceptive Pill.
  - If you are taking the **Pill** on the same day as Sugammadex 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 and follow the advice in the package leaflet.

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

Pregnancy and breast-feeding
Tell your anaesthetist if you are pregnant or might be pregnant or if you are breast-feeding,.

You may still be given Sugammadex , 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 to the mother.

Driving and using machines
Sugammadex has no known influence on your ability to drive and use machines.

Sugammadex contains sodium
Each pre-filled syringe of 5 ml contains to 30.8 mg sodium (main component of cooking / table salt). This is equivalent to 1.5 % of the recommended maximum daily dietary intake of sodium for an adult.

Each pre-filled syringe of 10 ml contains to 42.6 mg sodium (main component of cooking / table salt). This is equivalent to 2.1 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Sugammadex is given

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

The dose

Your anaesthetist will work out the dose of Sugammadex you need based on:
- your weight
- how much the muscle relaxant medicine is still affecting you.

The pre-filled syringe 100 mg/10 ml is more adapted to children and adults weighing less than 50 kg. In case of high doses or weights over 50 kg, other presentations or formulations are available.

The usual dose is 2-4 mg per kg body weight for adults and for children and adolescents between 2-17 years old. A dose of 16 mg/kg can be used in adults if urgent recovery from muscle relaxation is needed.

How Sugammadex is given
Sugammadex will be given to you by your anaesthetist. It is given as a single injection through an intravenous (into a vein) line.

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

If you have any further questions on the use of this medicine, ask your anaesthetist or other doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If these side effects occur while you are under anaesthesia, they will be seen and treated by your anaesthetist.

Common side effects (may affect up to 1 in 10 people)
- 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, so need more anaesthesia. 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

Uncommon side effects (may affect up to 1 in 100 people)
- 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, 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 can be life threatening.
  Allergic reactions were reported more commonly in healthy, conscious volunteers.
- Return of muscle relaxation after the operation.

Frequency not known
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when sugammadex is administered

Reporting of side effects
If you get any side effects, talk to your anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sugammadex

Storage will be handled by healthcare professionals.
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, on the blister and on the syringe label after 'EXP'. The expiry date refers to the last day of that month.

Do not freeze.

Keep the syringe in the outer carton in order to protect from light.

Keep the pre-filled syringe in its unopened blister until use.
After opening, the medicinal product must be used immediately.

Any pre-filled syringe, even partially used, should be discarded appropriately after use.
Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sugammadex contains

- The active substance is sugammadex
  Each ml of solution for injection contains sugammadex sodium equivalent to 50 mg sugammadex.
  Each 5 ml pre-filled syringe contains sugammadex sodium equivalent to 250 mg sugammadex.

  Each ml of solution for injection contains sugammadex sodium equivalent to 10 mg sugammadex.
  Each 10 ml pre-filled syringe contains sugammadex sodium equivalent to 100 mg sugammadex.

- The other ingredients are sodium chloride, hydrochloric acid or sodium hydroxide (for pH adjustment) and water for injections.

What Sugammadex looks like and contents of the pack

Sugammadex is a clear and colourless to slightly yellow solution for injection in a 5 ml polypropylene pre-filled syringe, with a graduated self- adhesive transparent label (sub - graduations of 0.2 ml from 0 until 5 ml). Each pre-filled syringe is individually packed in a transparent blister pack.

Sugammadex is a clear and colourless to slightly yellow solution for injection in a 10 ml polypropylene pre-filled syringe, with a graduated self- adhesive transparent label (sub - graduations of 0.5 ml from 0 until 10 ml). Each pre-filled syringe is individually packed in a transparent blister pack.

Cardboard boxes of 10 pre-filled syringes.

Marketing Authorisation Holder and Manufacturer

LABORATOIRE AGUETTANT
1, rue Alexander Fleming
69007 Lyon
France

This leaflet was last revised in 08/2023.

The following information is intended for healthcare professionals only:

Please prepare the syringe carefully as follows

The pre-filled syringe is for single patient only. Discard syringe after use. DO NOT REUSE.

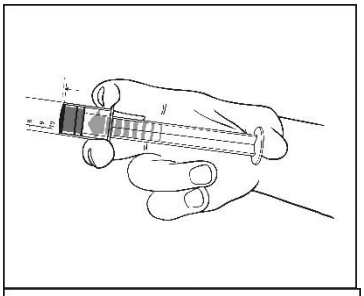
The content of an un-opened and un-damaged blister is sterile, and the blister must not be opened until the syringe is ready to be used.
The product should be inspected visually for particles and discoloration prior to administration. Only a clear colourless to slightly yellow solution free from particles or precipitates should be used.
The product should not be used if the tamper evident seal on the syringe is broken.
Do not use this medicine if you notice visible signs of deterioration.

The external surface of the syringe is sterile until the blister is opened. The blister must not be opened until use.

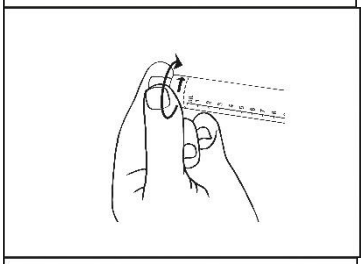
When handled using an aseptic method, this medicine can be placed on a sterile field once it has been removed from the blister.

The volume to be administer should be calculated regarding the appropriate posology.

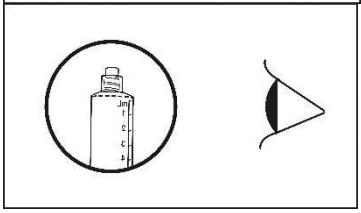
1) Withdraw the sterile pre-filled syringe from the blister.



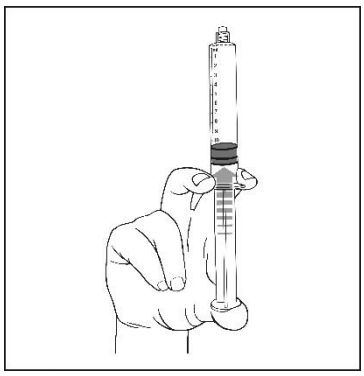
2) Push on the plunger to free the bung. The sterilisation process may have caused adhesion of the bung to the body of the syringe.



3) Twist off the end cap to break the seal. Do not touch the exposed luer connection in order to avoid contamination.



4) Check the syringe seal tip has been completely removed. If not, replace the cap and twist again.



5) Expel the air by gently pushing the plunger.

6) Connect the syringe to the vascular access device use a luer/luer lock system. Push the plunger slowly to inject the required volume. Administer the product according to the suitable administration route

The pre-filled syringe is not suitable for syringe pump drivers. The pre-filled syringe is a ready to administer product.

Any syringe that has been damaged or has been handled without respecting the conditions of sterility must not be used.
Any unused product or waste material should be disposed of in accordance with local requirements.