Package leaflet: Information for the user

Sugammadex100 mg/ml solution for injection
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 anaesthetist or doctor.
- If you get any side effects, talk to your anaesthetist 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 anaesthetist 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 if you take anticoagulation medicines.

Children
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 IntraUterine 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 this medicine.

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
This medicine contains up to 9.2 mg sodium (main component of cooking / table salt) in each ml. This is equivalent to 0.5 % 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 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.

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

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

If more Sugammadexis 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

Not known (frequency cannot be estimated from the available data)
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when Sugammadex is administered
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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.
Ireland
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 and on the label after "EXP". The expiry date refers to the last day of that month.
Keep the vial in the outer carton in order to protect from light.

After first opening and dilution, store at 2 to 8°C and use within 24 hours.

6. Contents of the pack and other information

What Sugammadex contains

- The active substance is sugammadex.
  1 ml solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex
  Each vial of 2 ml contains sugammadex sodium equivalent to 200 mg sugammadex.
  Each vial of 5 ml contains sugammadex sodium equivalent to 500 mg sugammadex.

- The other ingredients are water for injections, hydrochloric acid (to adjust pH) and/or sodium hydroxide (to adjust pH).

What Sugammadex looks like and contents of the pack
Sugammadex (injection) is a clear and colourless to slightly yellow-brown solution for injection. It is free from visible particles.

It comes in two different pack sizes, containing either 10 vials with 2 ml or 10 vials with 5 ml solution for injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Baxter Holding B.V.
Kobaltweg 49
3542CE Utrecht
Netherlands

Manufacturer
SOLUPHARM PHARMAZEUTISCHE ERZEUGNISSE GMBH
Industriestraße 3
34212 Melsungen, Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Country Name	Product Name
Ireland	Sugammadex 100 mg/ml Solution for Injection
Czech Republic	Sugammadex Baxter
Denmark	Sugammadex Baxter
Austria	Sugammadex Baxter 100 mg/ml Injektionslösung
Germany	Sugammadex Baxter 100 mg/ml Injektionslösung
Greece	Sugammadex/Baxter
Spain	Sugammadex Baxter 100 mg/ml solución inyectable EFG
Finland	Sugammadex Baxter 100 mg/ml injektioneste, liuos
France	Sugammadex Baxter 100 mg/ml, solution injectable
Italy	Sugammadex Baxter
Norway	Sugammadex Baxter
Belgium	Sugammadex Baxter 100 mg/ml solution injectable
Poland	Sugammadex Baxter
Portugal	Sugamadex Baxter
Romania	Sugammadex Baxter 100 mg/ml soluție injectabilă
Slovenia	Sugamadeks Baxter 100 mg/ml raztopina za injiciranje
Sweden	Sugammadex Baxter
Netherlands	Sugammadex Baxter 100 mg/ml oplossing voor injectie

This leaflet was last revised in June 2023

The following information is intended for healthcare professionals only:

For detailed information refer to the Summary of Product Characteristics of **Sugammadex100 mg/ml solution for injection**