PACKAGE LEAFLET: INFORMATION FOR THE USER

Sugammadex 100 mg/mL

solution for injection

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
2. What you need to know before Sugammadex is given
3. How Sugammadex is given
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

What Sugammadex is

Sugammadex 100 mg/mL solution for injection 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 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

This medicine contains 9.7 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.

Dose below or equal to 2.4 mL
A dose of 2.4 mL (or below) contains less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.

Dose above 2.4 mL
A dose of 2.4 mL (or more) contains 1 mmol (or more) sodium (23 mg).
This is equivalent to 1.15% (or more) 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 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

This medicine does not require any special temperature storage conditions.
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 is a clear, colourless to slightly yellow brown solution for injection, practically free from 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 and Manufacturer

Marketing Authorisation Holder:

Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL, United Kingdom

Manufacturer(s):

Synthon Hispania, SL
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Reading direction

Reading direction

CODE

Till-Ver.1.1

Product Name	**Sugammadex 100 mg/ml sol for inj**	**Sap code :**	**TBA**	**Reference Artwork**	**TW135889 (rel sites)**
Packaging Material	**Package leaflet**	**Reason of change :**	**TW147014 (redesign)**	**Proof 1**	**22/05/2024**
Size : Foil Width		**Country :**	**UK**	**Proof 2**	**23/05/2024**
Size : Foil Repeat Length		**Pack Size :**	**All**	**Proof 3**	**31/07/2024**
Size : Strip Size		**Barcode No. :**	**A**		
Size : PI - Open Size	**300 mm (W) x 378 mm (L)**	**Pharmacode :**	**TBA**		
Size : Carton/Label		**No. of colours :**	**1**		
PM Style/Type :		**Min. Font Size :**	**9 points (Reg text)**		
Remark (If any) :	**Release sites in this file are Synthon Hispania, SL & Tillomed UK. Other registered site is - Synthon B.V., Microweg 22, NIJMEGEN, 6545CM, Netherlands.**				

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