Package leaflet: Information for the user

Sugagelan 100 mg/ml oplossing voor injectie
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 any further questions, ask your anaesthetist or doctor.
- If you get any side effects, talk to your anaesthetist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Sugagelan is and what it is used for

What Sugagelan is

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

What Sugagelan 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.

Sugagelan 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 Sugagelan is given

You should not be given Sugagelan
- 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 Sugagelan is given
- if you have kidney disease or had in the past. This is important as Sugagelan 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 Sugagelan
Tell your anaesthetist if you are taking, have recently taken or might take any other medicines. Sugagelan may affect other medicines or be affected by them.

Some medicines reduce the effect of Sugagelan
It is especially important that you tell your anaesthetist if you have recently taken:
- toremifene (used to treat breast cancer).
- fusidic acid (an antibiotic).

Sugagelan can affect hormonal contraceptives
Sugagelan 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 Sugagelan is about the same as missing one oral contraceptive Pill.
- If you are taking the Pill on the same day as Sugagelan 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, Sugagelan 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 Sugagelan.

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 Sugagelan, 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 Sugagelan to the mother.

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

Sugagelan contains sodium

This medicine contains 9.7 mg sodium (main component of cooking/table salt) in each milliliter.

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.

Tell your anaesthetist if you are on a controlled salt diet.

3 How Sugagelan is given

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

If more Sugagelan 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 Sugagelan. 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 (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 (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 Sugagelan 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Sugagelan

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 Sugagelan 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 Sugagelan looks like and contents of the pack
Sugagelan 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.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning:
G.L. Pharma GmbH
Schlossplatz 1
8502 Lannach
Oostenrijk

Fabrikanten:
Synthon BV
Microweg 22
6545 CM Nijmegen
Nederland

Synthon Hispania S.L.
C/Castelló, n°1, Poligono Industrial Las Salinas
08830 Sant Boi de Llobregat, Barcelona
Spanje

In het register ingeschreven onder
RVG 128235

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte en in het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:

Nederland	Sugagelan 100 mg/ml oplossing voor injectie
Oostenrijk	Sugagelan 100 mg/ml-Injektionslösung

Deze bijsluiter is voor het laatst goedgekeurd in mei 2022