PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SUGAMMADEX 100 mg/ml MYLAN

Solution for injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given SUGAMMADEX 100 mg/ml MYLAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What SUGAMMADEX 100 mg/ml MYLAN is and what it is used for

SUGAMMADEX 100 mg/ml MYLAN contains the active substance sugammadex. SUGAMMADEX 100 mg/ml MYLAN is considered to be a selective relaxant

binding medicine since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

SUGAMMADEX 100 mg/ml MYLAN 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 (above 7 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before SUGAMMADEX 100 mg/ml MYLAN is administered to you

SUGAMMADEX 100 mg/ml MYLAN should not be administered to you:

- If you are hypersensitive (allergic) to sugammadex ion or any of the other ingredients of SUGAMMADEX 100 mg/ml MYLAN (listed in section 6).

Warnings and precautions

Talk to your anaesthetist before SUGAMMADEX 100 mg/ml MYLAN is given:

- if you have kidney disease or had in the past. This is important as SUGAMMADEX 100 mg/ml MYLAN 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

SUGAMMADEX 100 mg/ml MYLAN should not be given to children under 7 years of age.

Other medicines and SUGAMMADEX 100 mg/ml MYLAN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines reduce the effect of SUGAMMADEX 100 mg/ml MYLAN. 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 100 mg/ml MYLAN can affect hormonal contraceptives.

SUGAMMADEX 100 mg/ml MYLAN 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 100 mg/ml MYLAN is about the same as missing one oral contraceptive Pill.

If you are taking the Pill on the same day as SUGAMMADEX 100 mg/ml MYLAN 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 100 mg/ml MYLAN 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 100 mg/ml MYLAN.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

If you are pregnant or breastfeeding your baby, it is not advisable to receive SUGAMMADEX 100 mg/ml MYLAN. It is not known whether sugammadex can pass into breast milk.

Driving and using machines

SUGAMMADEX 100 mg/ml MYLAN has no known influence on your ability to drive and use machines.

SUGAMMADEX 100 mg/ml MYLAN contains sodium

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

3. How SUGAMMADEX 100 mg/ml MYLAN is administered

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself SUGAMMADEX 100 mg/ml MYLAN. It will be given to you by your anaesthetist, or under the care of your anaesthetist.

Your anaesthetist will work out the dose of SUGAMMADEX 100 mg/ml MYLAN 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 100 mg/ml MYLAN for children is 2 mg/kg (children and adolescents 7 to 17 years).

How SUGAMMADEX 100 mg/ml MYLAN is given:

SUGAMMADEX 100 mg/ml MYLAN will be given to you by your anaesthetist. It is given as a single injection through an intravenous line.

If you are given more SUGAMMADEX 100 mg/ml MYLAN than you should receive

As your anaesthetist will be monitoring your condition carefully, it is unlikely that you will be given too much SUGAMMADEX 100 mg/ml MYLAN.

4. Possible side effects

SUGAMMADEX 100 mg/ml MYLAN can have side effects.

Not all side effects reported for SUGAMMADEX 100 mg/ml MYLAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SUGAMMADEX 100 mg/ml MYLAN, please consult your health care provider for advice.

If these side effects occur while you are under anaesthetic or in ICU, they will be seen and treated by your anaesthetist, doctor or ICU nurse.

Tell your doctor if you notice any of the following:

Frequent

- a temporary unpleasant taste in your mouth;
- 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.

Less frequent

- shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems;
- allergic (medicine 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;
- 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 100 mg/ml MYLAN is administered.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SUGAMMADEX 100 mg/ml MYLAN.

5. How to store SUGAMMADEX 100 mg/ml MYLAN

Store all medicines out of reach of children.

Storage will be handled by healthcare professionals.

- Store at or below 25 °C.
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- Do not use after the expiry date stated on the carton or label.
- 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 100 mg/ml MYLAN contains

- The active substance is sugammadex.

  Each ml contains 100 mg sugammadex (as the sodium salt).

  Each 2 ml vial contains 200 mg sugammadex (as the sodium salt).

  Each ml contains 9,7 mg sodium.

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

What SUGAMMADEX 100 mg/ml MYLAN looks like and contents of the pack

SUGAMMADEX 100 mg/ml MYLAN is a clear and colourless to slightly yellow solution with pH of between 7 and 8.

SUGAMMADEX 100 mg/ml MYLAN is packed in colourless, glass vials, sealed with grey, chlorobutyl rubber stoppers firmly sealed with aluminium crimp-cap with polypropylene, “flush edge”, flip-off buttons. The rubber stoppers do not contain latex. Pack size: 10 vials of 2 ml..

Holder of Certificate of Registration

MYLAN (PTY) LTD

4 Brewery street

Isando

Gauteng

Republic of South Africa

This leaflet was last revised in

Registration number

55/36/0386.385

Access to the corresponding Professional Information