PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MYLADION 100 mg/mL

Solution for injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given MYLADION 100 mg/mL

- 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 MYLADION 100 mg/mL is and what it is used for

MYLADION 100 mg/mL contains the active substance sugammadex. MYLADION 100 mg/mL is considered to be a selective relaxant binding medicine since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide. MYLADION 100 mg/mL 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 MYLADION 100 mg/mL is administered to you

MYLADION 100 mg/mL should not be administered to you:

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

Warnings and precautions

Talk to your anaesthetist before MYLADION 100 mg/mL is given:

- if you have kidney disease or had in the past. This is important as MYLADION 100 mg/mL 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

MYLADION 100 mg/mL should not be given to children under 7 years of age.

Other medicines and MYLADION 100 mg/mL

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 MYLADION 100 mg/mL. It is especially important that you tell your anaesthetist if you have recently taken:

- toremifene (used to treat breast cancer).
- fusidic acid (an antibiotic).

MYLADION 100 mg/mL can affect hormonal contraceptives.

MYLADION 100 mg/mL 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 MYLADION 100 mg/mL is about the same as missing one oral contraceptive Pill.

If you are taking the Pill on the same day as MYLADION 100 mg/mL 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, MYLADION 100 mg/mL 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 MYLADION 100 mg/mL.

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 MYLADION 100 mg/mL. It is not known whether sugammadex can pass into breast milk.

Driving and using machines

MYLADION 100 mg/mL has no known influence on your ability to drive and use machines.

MYLADION 100 mg/mL contains sodium

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

3. How MYLADION 100 mg/mL is administered

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

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

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

How MYLADION 100 mg/mL is given:

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

If you are given more MYLADION 100 mg/mL than you should receive

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

4. Possible side effects

MYLADION 100 mg/mL can have side effects.

Not all side effects reported for MYLADION 100 mg/mL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving MYLADION 100 mg/mL, 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 MYLADION 100 mg/mL 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 MYLADION 100 mg/mL.

5. How to store MYLADION 100 mg/mL

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 MYLADION 100 mg/mL 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 MYLADION 100 mg/mL looks like and contents of the pack

MYLADION 100 mg/mL is a clear and colourless to slightly yellow solution with pH of between 7 and 8.

MYLADION 100 mg/mL 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

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Access to the corresponding Professional Information

To follow.