PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

SUMABID 100 IV

100 mg/mL solution for injection

(sugammadex)

(Sugar free)

This product contains 9,7 mg sodium (see section 6)

Read all of this leaflet carefully before you are given SUMABID.

- 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 **SUMABID** is and what it is used for
2. What you need to know before you are given **SUMABID**
3. How to use **SUMABID**
4. Possible side effects
5. How to store **SUMABID**
6. Contents of the pack and other information

1. What SUMABID is and what it is used for

What SUMABID is

SUMABID 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 SUMABID 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 ≥7 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before SUMABID is given to you

SUMABID should not be given to you:

- If you are hypersensitive (allergic) to sugammadex or any of the other ingredients of **SUMABID IV** (listed in section 6).

Tell your doctor if this applies to you.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- 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 are on a controlled salt diet.

- 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 children less than 7 years of age.

Other medicines and SUMABID

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

SUMABID may affect other medicines or be affected by them.

Some medicines reduce the effect of **SUMABID**

It is especially important that you tell your doctor or pharmacist if you have recently taken:

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

SUMABID can affect hormonal contraceptives.

- **SUMABID** can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal IntraUterine System (IUS) - less effective because it reduces the quantity of the progestogen hormone you get. 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 **SUMABID** is given to you, follow the instructions for a missed dose in the Pill's package insert.
  - 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 insert.

Effects on blood tests

In general, **SUMABID** does not have an effect on laboratory tests. However, it may affect the results of a blood test for a hormone called progesterone and some blood clotting tests. Talk to your doctor if your progesterone levels need to be tested on the same day you receive **SUMABID**.

Pregnancy, breastfeeding and fertility

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.

You may still be given **SUMABID**, but you need to discuss it first. It is not known whether **SUMABID** can pass into breast milk. Your doctor 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 **SUMABID** to the mother.

Driving and using machines

SUMABID has no known influence on your ability to drive and use machines. It is not always possible to predict to what extent **SUMABID** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **SUMABID** affects you.

3. How SUMABID is given

SUMABID will be given to you by your anaesthetist, or under the care of your anaesthetist.

The anaesthetist or healthcare professional will administer your correct dose.

The dose

Your anaesthetist will work out the dose of **SUMABID** you need based on:

- your weight

- how much the muscle relaxant medicine is still affecting you.

How **SUMABID** is given

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

Your doctor will tell you how long your treatment with **SUMABID** will last.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If more SUMABID 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 **SUMABID**. However, in the event of overdosage your doctor will manage the overdose.

If you have any further questions on the use of this medicine, ask your anaesthetist or other doctor.

If you forget to use SUMABID

Since a health care provider will administer **SUMABID**, it is unlikely that the dose will be missed.

If you stop using SUMABID

If treatment with **SUMABID** is interrupted, recovery of your muscles after an operation might not happen fast enough to allow you to breathe earlier on your own again.

4. Possible side effects

SUMABID can have side effects.

Not all side effects reported for **SUMABID** are included in this leaflet. Should your general health worsen or if you experience any untoward effects please consult your healthcare provider for advice.

If these side effects occur while you are under anaesthesia, they will be seen and

treated by your anaesthetist.

Serious side effects

If any of the following happens, tell your doctor immediately or go to the casualty department of your nearest hospital:

Less frequent side effects

- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to **SUMABID**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent side effects

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when **SUMABID** is administered

These are all serious side effects. You may need urgent medical attention.

Other side effects

Tell your doctor as soon as possible about any of the following side effects:

Frequent side effects

- Cough
- A temporary unpleasant taste in your mouth

- 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
- Your muscles may be weakened for longer than expected after the operation.

Less frequent side effects

- Return of muscle relaxation after the operation
- Being awake during the operation (anaesthesia awareness).

Other side effects not listed above may occur in some patients. 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 **SUMABID**.

5. How to store SUMABID

Store all medicines out of reach of children

Solution for injection:

Store at or below 25 °C.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Diluted solution for injection:

Store at 2 °C to 8 °C or below 25 °C.

6. Contents of the pack and other information

What SUMABID contains

The active ingredient is sugammadex.

The other ingredients are:

Water for Injection

Hydrogen Chloride or Sodium Hydroxide

Nitrogen

What SUMABID looks like and contents of the pack

SUMABID is packed in glass type I vials with a bromobutyl ruber stopper. On the vial an aluminium cap with flip top are applied. The aluminium cap is applied to tightly fix the rubber stopper to the glass vial.

Pack size: 10 vials of 2 mL packed in a carton box.

Holder of Certificate of Registration

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