APPROVED PATIENT INFORMATION LEAFLET
RBC PHARMACEUTICALS (PTY) LTD.
SUGAFLUX (Sugammadex sodium, Injection 100 mg/ mL)

SCHEDULING STATUS:

S4

SUGAFLUX (Injection 100 mg/ mL, 2 mL)

Sugammadex sodium

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- SUGAFLUX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What SUGAFLUX is and what it is used for.

The active substance of SUGAFLUX is Sugammadex sodium

SUGAFLUX is one of a group of medicines called selective relaxant binding agents since it only works with specific muscle relaxants, such as rocuronium bromide or vecuronium bromide.

When you have some type of operations, your muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic is given to make your muscles relax. These are called muscle relaxants. Because these medicines also make your breathing muscle relax, you

need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again.

SUGAFLUX 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 to 17 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before you are given SUGAFLUX.

SUGAFLUX should not be given to you if you:

- if you are hypersensitive (allergic) to sugammadex sodium or any of the other ingredients of SUGAFLUX (listed in section 6).

Warnings and precautions

Special care should be taken with SUGAFLUX:

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

- If you have kidney disease or have had it in the past. This is important as SUGAFLUX 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.
- if you have a slow heart rate (bradycardia).

Children and adolescents

SUGAFLUX is not be administered to patients below 7 years of age.

Other medicines and SUGAFLUX

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary, over-the-counter traditional medicines).

- Some medicines reduce the effect of SUGAFLUX:
- 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).

SUGAFLUX can affect hormonal contraceptives:

SUGAFLUX can make hormonal contraceptives including

- The 'pill'
- Vaginal ring
- Implants
- Hormonal intrauterine system (IUS)

less effective because it reduces how much you get of the progestogen hormone. The amount of progestogen lost by using SUGAFLUX is about the same as missing one oral contraceptive pill.

- If you are taking the pill on the same day as SUGAFLUX is given to you, follow the instruction 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.

Effects on blood tests:

- SUGAFLUX 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 SUGAFLUX.

Pregnancy, breast-feeding and fertility

Tell your anaesthetist If you are pregnant or might be a 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 receiving SUGAFLUX. You need to discuss it first.

The safety in pregnant women has not been established.

Breastfeeding

It is not known whether SUGAFLUX can pass into breast milk, however, based on animal studies, it is expected.

Driving and using machines

SUGAFLUX has no known influence on your ability to drive and use machines.

Patients should not drive, use machinery or perform tasks that require concentration until they are certain that SUGAFLUX does not adversely affect their ability to do so safely

Your doctor or pharmacist will tell you when it is safe to drive or operate machinery after you have been given SUGAFLUX.

SUGAFLUX contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium-free'.

3. How to receive SUGAFLUX

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

You will not be expected to give yourself SUGAFLUX. It will be given to you by a person who is qualified to do so. SUGAFLUX will be given into a vein (intravenously) as a single injection.

The usual dose is 2 to 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 SUGAFLUX for children is 2 mg/kg (children and adolescents between 7 to 17 years old).

If you are given more SUGAFLUX than you should receive

Since a healthcare professional will administer SUGAFLUX. they will control the dosage. However, if you are given more than the recommended dose your doctor will manage the overdosage.

If you forget to receive SUGAFLUX:

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

4. Possible side effects:

SUGAFLUX can have side effects.

Not all side effects reported for SUGAFLUX are included in this leaflet. Should your general health worsen while receiving SUGAFLUX, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop administration of SUGAFLUX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic (drug hypersensitivity) reactions- such as 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SUGAFLUX. 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:

Frequent side effects:

- Cough
- A temporary unpleasant taste in your mouth.
- Your muscle may be weakened for longer than expected after the operation.
- Airway difficulties that may include coughing or moving as if you are waking or taking a breath.
- Light anaesthetic – you may start to come out of deep sleep, so need more anaesthetic. This might cause you to move or cough at the end of the operation.
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUGAFLUX is administered.

Less frequent side effects:

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems;

- Being awake during the operation (anaesthesia awareness).

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

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, By reporting side effects, you can help provide more information on the safety of SUGAFLUX.

5. How to store SUGAFLUX

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 it from light.

After first opening and dilution, store at 2 to 8°C and use within 48 hours and 25 °C in diluents (Sodium Chloride, Dextrose, Sodium chloride and Dextrose, Ringer's lactate solution.

Keep the vials in the carton until required for use.

Do not use after the expiry date on the label and carton.

Do not use SUGAFLUX if the solution is cloudy has any colour or visible particles in it.

Do not throw medicines in drains or sewerage systems (e.g., toilets).

Return all unused and expired medicines to your pharmacist.

Keep all medicines out of reach and sight of children.

6. Contents of the pack and other information

What SUGAFLUX contains:

The active substance is sugammadex sodium.

Each mL contains 100 mg/ mL sugammadex sodium.

The other ingredients:

Hydrochloric acid

Sodium Hydroxide

Water for Injection

What SUGAFLUX looks like and contents of the pack:

Clear colourless to slightly yellow-brown solution filled in a vial.

SUGAFLUX is packed in It comes in two different pack sizes, containing either 10 vials with 2 mL

REGISTRATION NUMBER

57/17.3/0572

Holder of Certificate of Registration

RBC PHARMACEUTICALS (PTY) LTD.

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This leaflet was last revised on:

Date of registration: 28th July 2026

Date of the most recent revision: TBA

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: RBC PHARMACEUTICALS (PTY) LTD. Tel: +27 10 224 0999

Other sources of information

Detailed information on this medicine is available on the RBC PHARMACEUTICALS (PTY) LTD web site:

http://www.rbcpharma.com