PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SUBRAXX™,

200 mg/2 ml (100 mg/ml) solution for injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given SUBRAXX

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

What is in this leaflet

1. What SUBRAXX is and what it is used for

What SUBRAXX is

SUBRAXX contains the active substance sugammadex (as sugammadex sodium).

SUBRAXX is one of a group of medicines called Selective Relaxant Binding Agents (SRBA's), since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

What SUBRAXX is used for

SUBRAXX is given to speed up your recovery from the muscle relaxant which is part of the anaesthetic regimen to allow the surgeon to do the operation. SUBRAXX will be given to you at the end of an operation to allow you to breathe normally earlier.

It can be used in adults whenever rocuronium bromide or vecuronium bromide is used and in children and adolescents (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 SUBRAXX

SUBRAXX should not be given to you:

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

Warnings and precautions

Tell your doctor or healthcare provider before you are given SUBRAXX:

- if you have kidney disease or had in the past. This is important as SUBRAXX is removed from your body by the kidneys
- if you have fluid retention (oedema) or a heart disease
- if you have liver disease or have had it in the past
- if you have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or if you use anticoagulation medicines (such as rivaroxaban and dabigatran)
- if you are on a salt-controlled diet (see **SUBRAXX contains sodium** below).

Children and adolescents

This medicine is only recommended for children and adolescents above 7 years of age.

Other medicines and SUBRAXX

Always tell your healthcare provider if you are taking any other medicine.

This includes all complementary or traditional medicines.

Some medicines reduce the effect of SUBRAXX

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

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

SUBRAXX can reduce the efficacy of hormonal contraceptives

SUBRAXX can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal intra uterine system (IUS) less effective because it reduces how much you get of the progestogen hormone.

The amount of progestogen lost by using SUBRAXX is about the same as missing one oral contraceptive Pill.

- If you are taking the Pill on the same day as SUBRAXX is given to you, follow the instructions for a missed dose in the Pill's patient information 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 patient information leaflet.

Effects on blood tests

In general, SUBRAXX 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 SUBRAXX.

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 healthcare provider for advice before receiving this medicine.

It is not known whether sugammadex can pass into breastmilk.

Driving and using machines

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

It is not always possible to predict to what extent SUBRAXX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SUBRAXX affects them.

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

SUBRAXX contains sodium

SUBRAXX contains up to 9,7 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,5 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How SUBRAXX is given

You will not be expected to give yourself SUBRAXX. It will be given to you by a person who is qualified to do so.

SUBRAXX will be given to you into a vein (intravenously) by your doctor.

Your doctor will work out the dose of SUBRAXX you need, based on your weight and on how much the muscle relaxant medicine is still affecting you.

The usual adult dose is 2 to 4 mg per kg body weight.

The usual dose in children (7 to 17 years old) is 2 mg/kg body weight.

If more SUBRAXX is given to you than recommended

Since a healthcare provider will administer SUBRAXX, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use SUBRAXX

Since a healthcare provider will administer SUBRAXX, it is unlikely that the dose will be missed.

4. Possible side effects

SUBRAXX can have side effects.

Should your general health worsen or if you experience any untoward effects while receiving SUBRAXX, they will be seen and treated by your doctor. If

you have any untoward effects after the operation, please consult your healthcare provider for advice.

Not all side effects reported for SUBRAXX are included in this leaflet.

The following serious side effects may occur while you are under anaesthesia. Your doctor will see them and treat you immediately:

- Allergic (hypersensitivity) reactions may include a rash or red skin, swelling of your tongue and/or throat, 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.

Frequent side effects

- A temporary unpleasant taste in your mouth, headache
- Cough
- 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
- Your muscles may be weakened for longer than expected after the operation
- Being awake during the operation (anaesthesia awareness)
- Decreased blood pressure due to the surgical procedure
- Complications during your procedure such as changes in heartrate, coughing or moving

- Return of muscle relaxation after the operation.

Frequency not known

- Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of asthma
- Dizziness
- Nausea, vomiting, abdominal pain
- Hives, red skin, itching skin
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUBRAXX is administered.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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 SUBRAXX.

5. How to store SUBRAXX

Storage will be handled by healthcare providers.

Store all medicines out of reach of children.

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 this medicine after the expiry date which is stated on the carton and on the label. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What SUBRAXX contains

- The active substance is sugammadex. 1 ml solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex (as sugammadex sodium). Each vial of 2 ml contains sugammadex sodium equivalent to 200 mg sugammadex.
- The other ingredient is water for injection.

What SUBRAXX looks like and contents of the pack

SUBRAXX is a clear and colourless to slightly yellow-brown solution for injection.

SUBRAXX is packaged in a 2 ml clear, type I glass vial with a butyl rubber stopper and aluminium plastic cap.

Pack sizes: 1 or 10 vials of 2 ml

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised

20 August 2025

Registration number

57/32.16/0239