PATIENT INFORMATION LEAFLET (PIL)

SCHEDULING STATUS: S4

SUGAMMADEX 100 mg/1 mL FRESENIUS solution for injection

SUGAMMADEX 200 mg/2 mL FRESENIUS solution for injection

SUGAMMADEX 500 mg/5 mL FRESENIUS solution for injection

Sugammadex

Sugar free

Read all of this leaflet carefully before you are given SUGAMMADEX FRESENIUS

- 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 SUGAMMADEX FRESENIUS is and what it is used for
2. What you need to know before SUGAMMADEX FRESENIUS is administered to you
3. How SUGAMMADEX FRESENIUS is administered to you
4. Possible side effects
5. How to store SUGAMMADEX FRESENIUS
6. Contents of the pack and other information

1. What SUGAMMADEX FRESENIUS is and what it is used for

SUGAMMADEX FRESENIUS belongs to a group of medicines called Selective Relaxant Binding Agents (SRBA's).

To make your muscles relax during an operation your doctor can use muscle relaxants such as rocuronium or vecuronium. Because the muscles needed for breathing also become relaxed, you will need help with your breathing (artificial ventilation) during and after your operation until you can breathe on your own again. SUGAMMADEX FRESENIUS stops the working of the muscle relaxants by combining with rocuronium or vecuronium in your body.

SUGAMMADEX FRESENIUS is given to speed up your recovery from the muscle relaxant, for example, at the end of an operation to allow you to breathe normally earlier.

Children and adolescents:

SUGAMMADEX FRESENIUS is only recommended for children above 7 years of age.

2. What you need to know before SUGAMMADEX FRESENIUS is administered to you

SUGAMMADEX FRESENIUS should not be administered to you:

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

Warnings and precautions

Tell your doctor before SUGAMMADEX FRESENIUS is given:

- if you have kidney disease or had in the past. This is important as SUGAMMADEX FRESENIUS 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 a heart disease (this may delay recovery)
- if you have a history of bleeding episodes or diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or if you take medicines to prevent blood clotting (such as rivaroxaban and dabigatran)
- if you are on a salt-controlled diet (see below **SUGAMMADEX FRESENIUS contains salt**).

Other medicines and SUGAMMADEX FRESENIUS

Always tell your healthcare provider (doctor, nurse, pharmacist or other) if you are taking any other medicine (This includes all complementary or traditional medicines.).

Some medicines reduce the effect of SUGAMMADEX FRESENIUS:

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

• toremifene (used to treat breast cancer).

• fusidic acid (an antibiotic).

SUGAMMADEX FRESENIUS can affect hormonal contraceptives

SUGAMMADEX FRESENIUS 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 SUGAMMADEX FRESENIUS is about the same as missing one oral contraceptive Pill.

- If you are taking the Pill on the same day as SUGAMMADEX FRESENIUS 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

SUGAMMADEX FRESENIUS 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 FRESENIUS.

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, nurse, 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

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

Your doctor will tell you when it is safe to drive or operate machinery after you have been given SUGAMMADEX FRESENIUS. It is not always possible to predict to what extent SUGAMMADEX FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not undertake the above activities until they are aware of the measure to which SUGAMMADEX FRESENIUS affects them.

You should not drive, use machinery or perform any tasks that require concentration until you are certain that SUGGAMADEX FRESENIUS does not adversely affect your ability to do so safely.

SUGAMMADEX FRESENIUS contains salt

SUGAMMADEX FRESENIUS 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 SUGAMMADEX FRESENIUS is administered to you

You will not be expected to give yourself SUGAMMADEX FRESENIUS.

SUGAMMADEX FRESENIUS will be given to you by the doctor in the theatre. It is given as a single injection through an intravenous line.

Your doctor will decide what dose of SUGAMMADEX FRESENIUS you need. This will depend 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 SUGAMMADEX FRESENIUS is administered to you than recommended

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

4. Possible side effects

SUGAMMADEX FRESENIUS can have side effects.

Not all side effects reported for SUGAMMADEX FRESENIUS are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while SUGAMMADEX FRESENIUS is administered, 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.

The following serious side effects may occur while you are having the operation. 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

- An unpleasant taste in your mouth
- Headache
- 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 anaesthetic. 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), especially in asthmatics
- Dizziness
- Nausea, vomiting, abdominal pain
- Itching skin, red skin, hives
- Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUGAMMADEX FRESENIUS is administered.

If after your operation, 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SUGAMMADEX FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store SUGAMMADEX FRESENIUS

Store all medicines out of reach of children.

Store at or below 30 °C. Do not freeze. Keep the vial in the outer carton in order to protect from light.

Storage will be handled by healthcare providers.

Do not use this medicine after the expiry date which is stated on the carton and on the label after 'EXP'. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What SUGAMMADEX FRESENIUS contains

- **The active substance** is sugammadex.

1 mL solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex.

Each vial of 2 mL contains sugammadex sodium equivalent to 200 mg sugammadex.

Each vial of 5 mL contains sugammadex sodium equivalent to 500 mg sugammadex.

- **The other ingredients** are water for injection, hydrochloric acid and/or sodium hydroxide (for adjustment of pH).

What SUGAMMADEX FRESENIUS looks like and contents of the pack

SUGAMMADEX FRESENIUS is a clear and colourless to slightly yellow solution.

SUGAMMADEX 100 mg/1 mL FRESENIUS and SUGAMMADEX 200 mg/2 mL FRESENIUS are packed in 2 mL, Ph. Eur. Type-1, tubular clear glass vials, stoppered with 13 mm chlorobutyl grey rubber stoppers and sealed with 20 mm aluminium flip-off overseal.

Pack sizes: 10 vials per carton

Not all pack sizes may be marketed.

SUGAMMADEX 500 mg/5 mL FRESENIUS is packed in 6 mL, Ph. Eur. Type-1, tubular clear glass vials, stoppered with 20 mm chlorobutyl grey rubber stoppers and sealed with 20 mm aluminium flip-off overseal.

Pack sizes: 10 vials per carton

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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SUGAMMADEX 200 mg/2 mL FRESENIUS: 56/34/0944

SUGAMMADEX 500 mg/5 mL FRESENIUS: 56/34/0945

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.