

PATIENT INFORMATION LEAFLET

SUGAVER 200 mg/2 mL I.V. solution for injection

Sterile

Administered intravenously

Active ingredient: 2 mL solution contains 250 mg sugammadex sodium equivalent to 200 mg sugammadex.

Excipients: Hydrochloric acid, sodium hydroxide, water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*
- *This drug can only be administered by healthcare professionals in hospitals, during surgery.*

It is not for individual use.

What is in this leaflet:

1. *What is SUGAVER and what is it used for?*
2. *What you need to know before you use SUGAVER?*
3. *How to use SUGAVER?*
4. *Possible side effects*
5. *How to store SUGAVER?*

Headings are covered.

1. What is SUGAVER and what is it used for?

SUGAVER contains sugammadex as active ingredient.

- SUGAVER is considered to be a selective relaxant binding agent since it only works with specific muscle relaxants (rocuronium bromide and vecuronium bromide).
- SUGAVER is presented in boxes containing 10 amber colored ampoules of 2 mL. 1 mL SUGAVER contains 100 mg sugammadex.
- SUGAVER is used to restore your muscles to function after surgery.

When you are going to have some types of surgery, your muscles need to be completely relaxed. Relaxing your muscles makes it easier for your doctor to perform the surgery. For this purpose, your muscles are relaxed by using drugs that provide anesthesia in the whole body. These are called muscle relaxants and, for example, rocuronium bromide and vecuronium bromide are such drugs. Since these drugs also relax your breathing muscles, you will need help with breathing during and after surgery (artificial ventilation) until you can breathe again on your own.

SUGAVER is used to accelerate the recovery of your muscles after surgery to allow you to breathe on your own again. SUGAVER achieve this by combining with rocuronium bromide or vecuronium bromide in your body. SUGAVER can be used in all cases where rocuronium bromide or vecuronium bromide is used in adults, and when rocuronium bromide is used for moderate relaxation in children and adolescents (aged 2-17 years).

2. What you need to know before you use SUGAVER?

DO NOT USE SUGAVER;

If you are hypersensitive to sugammadex or other substances in SUGAVER, tell your anesthesiologist about this condition.

USE SUGAVER CAREFULLY;

If;

- you have had kidney disease in the past or are currently experiencing it, because SUGAVER is excreted from the body through the kidneys,
- you have had liver disease in the past or if you currently have liver disease,
- you have edema,
- you have diseases that are known to increase the risk of bleeding (disorders of blood clotting) or if you are taking anticoagulants.

Tell your anesthesiologist about these conditions.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Children and adolescents

This drug is not recommended for babies under 2 years of age.

Use of SUGAVER with food and drink

For SUGAVER, which is used to breathe on its own during surgery and after surgery, your doctor or anesthesiologist will advise you that you should be hungry because we didn't eat or drink anything before the operation.

Pregnancy

Consult your doctor or your pharmacist before using the drug.

If you are pregnant or not sure if you are pregnant or if you are breastfeeding, tell your anesthesiologist about this condition.

You can still take SUGAVER even if you are pregnant, but firstly you should discuss this with your doctor. It is not known whether sugammadex passes into breast milk. Your anesthesiologist will help you decide whether to discontinue breastfeeding or discontinue sugammadex therapy, taking into account the benefit of breastfeeding the baby and the benefit of **SUGAVER** for the mother's treatment.

If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.

Lactation

Consult your doctor or pharmacist before using the drug.

If you are breastfeeding, tell your anesthesiologist about this.

SUGAVER can be used during breastfeeding.

Driving and using machines

SUGAVER has no known effects on the ability to drive and use machines.

Important information about some excipients present in SUGAVER

Each 1 mL of the solution contains 9.7 mg of sodium. This medicine contains less than 1 mmol (23 mg) of sodium in each 1 mL; it is essentially "sodium-free". If administration of 2.4 mL solution is required, consideration should be given to whether the patient is on a controlled sodium diet. Tell your anesthesiologist if you are on a controlled sodium diet.

Use with other medicines

SUGAVER and some other medicines may interact with each other. Tell your anesthesiologist about any prescription or non-prescription medications you are currently taking or have recently taken.

Some medicines reduce the effect of SUGAVER.

It is important to tell your anesthesiologist if you have recently taken the following drugs:

- Toremifene (used to treat breast cancer)
- Fusidic acid (a type of antibiotic)

SUGAVER can affect hormonal contraceptives.

Because SUGAVER reduces the progestogen hormone (a type of reproductive hormone) produced in your body, it may cause hormonal contraceptives, including the pill, vaginal ring,

implant, or hormonal IUD, to be less effective. The amount of reduction in progestogen hormone associated with the use of SUGAVER is equivalent to skipping a dose of oral contraceptives (birth control medication).

→ If you take the pill on the day you take SUGAVER, follow the steps to be taken in case of a missed dose in the patient information leaflet.

→ If you are using other hormonal contraceptive methods (for example, a vaginal ring, implant or IUD), you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days.

Effects on blood tests

In general, SUGAVER has no effect on laboratory tests. However, it can 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 day you take SUGAVER.

If you are currently using any prescription or non-prescription medication or you have used it recently, please inform your doctor or pharmacist about them.

3. How to use SUGAVER?

SUGAVER will be given to you by or under the supervision of an anesthesiologist.

Instructions for appropriate use and dose/administration frequency:

Your anesthesiologist will give you the dose of SUGAVER you need based on your weight and how much muscle relaxant will work on you.

The usual dose is 2 to 4 mg per kilogram of body weight. If immediate recovery is required after muscle relaxant, a dose of 16 mg/kg may be used.

Route and Method of administration:

SUGAVER will be given intravenously as a single injection by your anesthesiologist.

Various age groups:

Pediatric use:

The dose of SUGAVER for children is 2 mg/kg (for children and adolescents aged 2-17).

Geriatric Use:

The same dose recommendation should be followed for the elderly as for adults.

Special use cases:

Kidney failure and liver failure

Dosage recommendations for patients with mild to moderate renal or hepatic impairment are the same as for adults.

However, SUGAVER should not be used in severe renal failure.

Talk to your doctor or pharmacist if you have the impression that the effect of SUGAVER is too strong or weak.

If you have used more SUGAVER than you should

It is not possible to take large amounts of SUGAVER as your anesthesiologist will monitor your condition carefully. However, if such a situation occurs, it will not cause any problems.

If you forget to use SUGAVER

Your anesthesiologist will administer **SUGAVER** to you.

4. Possible side effects

Like all medicines, SUGAVER can cause side effects, but not for everyone.

If side effects occur while you are being anesthetized, these side effects will be noticed and treated by your anesthesiologist.

Side effects are listed as shown in the following categories:

Very Common	: Effects at least 1 in 10 patients
Common	: Effects less than one in 10 patients, but more than one in 100 patients
Uncommon	: Effects less than one in 100 patients, but more than one in 1,000 patients
Rare	: Effects less than one in 1,000 patients, but more than one in 10,000 patients.
Very Rare	: Effects less than one in 10,000 patients.
Unknown	: Cannot be estimated from the available data

Common

- Cough
- Respiratory tract problems; coughing or acting as if waking or breathing
- Mild Anesthesia - It will cause you to come out of deep sleep and you may need more anesthesia. This may cause you to move or cough at the end of the surgery.
- Conditions that occur during the procedure, such as changes in heartbeat, coughing or movement
- Low blood pressure due to surgical procedure

Uncommon:

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

- Allergic (drug-induced hypersensitivity reactions) - e.g., rash and redness of the skin, swelling of the tongue and/or throat, changes in blood pressure or heart rate, sometimes resulting in a severe reduction in blood pressure. Severe allergic or allergy-like reactions can be life-threatening. Allergic reactions were more commonly reported in healthy, conscious volunteers.
- Recovery of muscle relaxation after surgery

Unknown:

- When SUGAVER is administered, serious slowing of the heart and slowing of the heart to the stopping (cardiac arrest) may be observed.

If you notice any side effects getting worse after the surgery, or if you experience a side effect not included in this list, inform your doctor or anesthesiologist immediately.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store SUGAVER?

Keep SUGAVER out of the reach and sight of children and within its packaging.

This product is stored by health-care professionals.

Store at room temperature below 30°C.

Do not freeze.

The ampoule should be stored in the outer carton box to protect it from light.

Product can be diluted with; 0.9% NaCl solution; 0.9% NaCl and 5% dextrose solution; 0.45% NaCl and 2.5% Dextrose solution; 5% Dextrose solution; Ringer's lactate solution and Ringer's solution.

After first opening and dilution, it can be used within 24 hours at 2°C-8°C. The opened ampoule is for single use only and must be used immediately.

Use in compliance with the expiry date.

Do not use SUGAVER after the expiry date on the ampoule and carton box. Use in compliance with the expiry date.

Do not throw away expired or unused drugs! Give it to the collection system determined by the relevant Local Authority.

Marketing Authorization Holder:

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Akbaba Mah. Maraş Cad. No: 52/2/1
Beykoz/İSTANBUL

Manufacturing Site

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