

SUGAMMADEX SANDOZ®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Sugammadex Sandoz?

Sugammadex Sandoz contains the active ingredient sugammadex. Sugammadex Sandoz is used to speed up recovery of your muscles after an operation.

For more information, see Section [1. Why am I given Sugammadex Sandoz?](#) in the full CMI.

2. What should I know before Sugammadex Sandoz is given?

Do not use if you have ever had an allergic reaction to Sugammadex Sandoz or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Sugammadex Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sugammadex Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How Sugammadex Sandoz is given?

- Sugammadex Sandoz is given as an injection into your vein (intravenously) as a single injection.
- The doctor will work out the dose of Sugammadex Sandoz you need based on your weight and how much muscle relaxant is still affecting you.

More instructions can be found in Section [4. How Sugammadex Sandoz is given?](#) in the full CMI.

5. What should I know while Sugammadex Sandoz is given?

Driving or using machines	<ul style="list-style-type: none">• Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery.
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For more information, see Section [5. What should I know while Sugammadex Sandoz is given?](#) in the full CMI.

6. Are there any side effects?

If side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SUGAMMADEX SANDOZ®

Active ingredient(s): *sugammadex*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sugammadex Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Sugammadex Sandoz.**

Where to find information in this leaflet:

- [1. Why am I given Sugammadex Sandoz?](#)
- [2. What should I know before I am given Sugammadex Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How Sugammadex Sandoz is given?](#)
- [5. What should I know while Sugammadex Sandoz is given?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given Sugammadex Sandoz?

Sugammadex Sandoz contains the active ingredient sugammadex. Sugammadex is a Selective Relaxant Binding Agent. It is used to speed up recovery of your muscles after an operation.

During some operations, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation. To make your muscles relax, the general anaesthetic includes 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 Sandoz is used to stop the muscle relaxants working. It does this by combining with rocuronium or vecuronium in your body.

Sugammadex Sandoz 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.

You may already have been given Sugammadex Sandoz. Your doctor will have considered the situation carefully and decided to use it.

Your doctor will have explained why you are being treated with Sugammadex Sandoz

Ask your doctor if you want any more information about this medicine.

Sugammadex Sandoz is not addictive.

2. What should I know before I am given Sugammadex Sandoz?

Warnings

You must not be given Sugammadex Sandoz if:

- you are allergic to sugammadex, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing of difficulty breathing
 - swelling of the tongue and/or throat
 - rash or red skin

Check with your doctor if you:

- have kidney disease or have had it in the past. This is important because Sugammadex Sandoz is removed from your body by the kidneys.
- have any diseases known to give an increased risk of bleeding (disturbance of blood clotting)
- have liver disease or have had it in the past
- have fluid retention (oedema)
- have allergies to other medicines or any other substances, such as foods, preservatives or dyes
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using Sugammadex Sandoz if you are pregnant or breastfeeding.

Children under age of 2

Sugammadex Sandoz is not recommended for infants less than 2 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Sugammadex Sandoz and affect how it works.

Medicines that may reduce the effect of Sugammadex Sandoz include:

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

Sugammadex Sandoz may reduce the effect of hormonal contraceptives.

Tell your doctor if you are using a hormonal contraceptive such as the "PILL", vaginal ring, implants or hormonal Intrauterine System (IUS).

Sugammadex Sandoz can make hormonal contraceptives less effective because it reduces how much you get of the hormone progestogen. The amount of progestogen lost by using Sugammadex Sandoz is about the same as missing one oral contraceptive Pill.

If you are taking the PILL the same day as Sugammadex Sandoz is given to you, follow the instructions for a missed dose in the Pill's package insert.

If you are using OTHER hormonal contraceptives (such as a vaginal ring, implant or IUS), you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days.

Laboratory tests: In general, Sugammadex Sandoz does not have an effect on laboratory tests. However it may affect the results of a blood test for a hormone called progesterone.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sugammadex Sandoz.

4. How Sugammadex Sandoz is given?

How much is given

Sugammadex Sandoz is given as an injection into your vein (intravenously) as a single injection.

The doctor will work out the dose of Sugammadex Sandoz you need based on:

- your weight
- how much muscle relaxant is still affecting you

The usual dose is 2 - 4 mg per kg body weight for patients 2 years of age and older. A dose of 16 mg per kg can be used only in adults if urgent recovery from muscle relaxation is needed.

If you are given too much Sugammadex Sandoz

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much Sugammadex Sandoz. Even if this happens, it is unlikely to cause any problems.

5. What should I know while using Sugammadex Sandoz?

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Sugammadex Sandoz affects you.

Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery. As far as it is known, Sugammadex Sandoz has no effect on alertness or concentration.

Looking after your medicine

Sugammadex Sandoz is stored in the hospital according to the storage conditions on the pack.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Signs and symptoms of lung problems:</p> <ul style="list-style-type: none">• Cough.• Airway difficulties that may include coughing or moving as if you are waking or taking a breath.• Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems.	<p>If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist. If after your operation, you notice any side effects tell your doctor.</p>
<p>Signs and symptoms of heart problems:</p> <ul style="list-style-type: none">• Decreased blood pressure due to the procedure.	
<p>Signs and symptoms of allergic reactions:</p> <ul style="list-style-type: none">• Allergic reactions such as a rash or red skin, swelling of the tongue and/or throat, shortness of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease in blood pressure. Severe allergic or allergic-like reactions can be life threatening. Allergic reactions were reported more commonly in healthy, conscious volunteers.	

<p>Signs and symptoms of muscle problems:</p> <ul style="list-style-type: none"> Return of muscle relaxation after the operation. <p>Signs and symptoms problems in other organs:</p> <ul style="list-style-type: none"> Light anaesthesia - you may start to come out of deep sleep and need more anaesthetic. 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. Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when Sugammadex Sandoz is administered. 	
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What Sugammadex Sandoz looks like

Sugammadex Sandoz 200 mg/2 mL is a colourless to slightly yellow solution for injection. (AUST R 359976)

Sugammadex Sandoz 500 mg/5 mL is a colourless to slightly yellow solution for injection. (AUST R 359975)

Who distributes Sugammadex Sandoz

Sandoz Pty Ltd

100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

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If after your operation, you notice any side effects tell your doctor.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Sugammadex Sandoz contains

Active ingredient (main ingredient)	sugammadex
Other ingredients (inactive ingredients)	hydrochloric acid sodium hydroxide water for injections

Do not take this medicine if you are allergic to any of these ingredients.