

SUGAMMADEX MEDSURGE

Solution for Injection

▼ 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 using SUGAMMADEX MEDSURGE?

SUGAMMADEX MEDSURGE contains the active ingredient Sugammadex (as sodium salt). SUGAMMADEX MEDSURGE is used to speed up recovery of your muscles after an operation.

For more information, see Section [1. Why am I using SUGAMMADEX MEDSURGE?](#) in the full CMI.

2. What should I know before I use SUGAMMADEX MEDSURGE?

Do not use if you have ever had an allergic reaction to Sugammadex 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 use SUGAMMADEX MEDSURGE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SUGAMMADEX MEDSURGE 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 do I use SUGAMMADEX MEDSURGE?

- SUGAMMADEX MEDSURGE is given as a single injection through an intravenous line.

More instructions can be found in Section [4. How do I use SUGAMMADEX MEDSURGE?](#) in the full CMI.

5. What should I know while using SUGAMMADEX MEDSURGE?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you are taking or have recently taken: toremifene, fusidic acid, flucloxacillin. These medicines can reduce the effect of SUGAMMADEX MEDSURGE.• Tell your doctor if you are using a hormonal contraceptive such as the "PILL", vaginal ring, implants or hormonal Intrauterine System (IUS).• If after your operation, you notice any side effects tell your doctor.• Tell your doctor if you notice anything that is making you feel unwell.• Ask your doctor to answer any questions you may have.
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.• As far as it is known, SUGAMMADEX MEDSURGE has no effect on alertness or concentration.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C. Do not freeze. Protect from light.• Contains no antimicrobial agent. Product is for single use in one patient only. Discard any residue.• The diluted product should be used immediately.

For more information, see Section [5. What should I know while using SUGAMMADEX MEDSURGE?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given SUGAMMADEX MEDSURGE. Side effects of SUGAMMADEX MEDSURGE include Cough, Airway difficulties, Light anaesthesia, Complications during your procedure such as changes in heart rate, coughing or moving, Decreased blood pressure due to the procedure, 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.

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 MEDSURGE Solution for Injection

Active ingredient(s): *Sugammadex*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SUGAMMADEX MEDSURGE. **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 MEDSURGE.**

Where to find information in this leaflet:

- [1. Why am I using SUGAMMADEX MEDSURGE?](#)
- [2. What should I know before I use SUGAMMADEX MEDSURGE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SUGAMMADEX MEDSURGE?](#)
- [5. What should I know while using SUGAMMADEX MEDSURGE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SUGAMMADEX MEDSURGE?

SUGAMMADEX MEDSURGE contains the active ingredient Sugammadex (as sodium salt). Sugammadex belongs to a group of medicines called Selective Relaxant Binding Agents. SUGAMMADEX MEDSURGE is used to stop the muscle relaxants working. It does this by combining with rocuronium or vecuronium in your body.

SUGAMMADEX MEDSURGE 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 MEDSURGE 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.

Your doctor will have explained why you are being treated with SUGAMMADEX MEDSURGE.

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

SUGAMMADEX MEDSURGE is not addictive.

2. What should I know before I use SUGAMMADEX MEDSURGE?

Warnings

Do not use SUGAMMADEX MEDSURGE if:

- you are allergic to SUGAMMADEX MEDSURGE, 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 or difficulty breathing
 - swelling of the tongue and/or throat

Check with your doctor if you:

- **have if you have kidney disease or have had it in the past.** This is important because SUGAMMADEX MEDSURGE 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.**
- **Tell your doctor if you have fluid retention (oedema).**
- **Tell your doctor if you have allergies to:**
 - any other medicines
 - 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 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 MEDSURGE if you are pregnant or breastfeeding.

SUGAMMADEX MEDSURGE is not recommended for infants less than 2 years of age.

If you have not told your doctor about any of the above, tell them before you are given SUGAMMADEX MEDSURGE.

Using 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 MEDSURGE can make hormonal contraceptives less effective because it reduces how much you get of the hormone progesterone. The amount of progesterone lost by using SUGAMMADEX MEDSURGE is about the same as missing one oral contraceptive Pill.
- If you are taking the PILL the same day as SUGAMMADEX MEDSURGE 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 MEDSURGE does not have an effect on laboratory tests. However it may affect the results of a blood test for a hormone called progesterone.

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 MEDSURGE and affect how it works.

Tell your doctor if you are taking or have recently taken:

Medicines that may reduce the effect of SUGAMMADEX MEDSURGE include:

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

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 MEDSURGE.

4. How do I use SUGAMMADEX MEDSURGE?

How much to take / use

- SUGAMMADEX MEDSURGE is given as a single injection through an intravenous line.
- The doctor will work out the dose of SUGAMMADEX MEDSURGE 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. A dose of 16 mg per kg can be used only in adults if urgent recovery from muscle relaxation is needed.
- The dose of SUGAMMADEX MEDSURGE for children and adolescents between 2-17 years old is 2 mg per kg.

When to take / use SUGAMMADEX MEDSURGE

- SUGAMMADEX MEDSURGE should be used to speed up recovery of your muscles after an operation.

If you use too much SUGAMMADEX MEDSURGE

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

If you think that you have used too much SUGAMMADEX MEDSURGE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **by calling 13 11 26** for Australia and **0800 (POISON) (0800 764 766)** for New Zealand, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SUGAMMADEX MEDSURGE?

You may already have been given SUGAMMADEX MEDSURGE injection. Your doctor will have considered the situation carefully and decided to use it.

Things you should do

Tell your doctor:

- If after your operation, you notice any side effects.
- If you notice anything that is making you feel unwell.
- Ask your doctor to answer any questions you may have.

Things you should not do

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SUGAMMADEX MEDSURGE affects you.

As far as it is known, SUGAMMADEX MEDSURGE has no effect on alertness or concentration.

Looking after your medicine

- Store below 30°C. Do not freeze. Protect from light.
- Contains no antimicrobial agent. Product is for single use in one patient only. Discard any residue.
- From a microbiological viewpoint, the diluted product should be used immediately.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• 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 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.• Decreased blood pressure due to the procedure.• 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.• Shortness of breath due to muscle cramps of the airway (bronchospasm) occurred in patients with a history of lung problems.• Return of muscle relaxation after the operation.• Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUGAMMADEX MEDSURGE is administered.	<p>Speak to your doctor if you have any of these side effects and they worry you.</p> <p>If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.</p> <p>If after your operation, you notice any side effects tell your doctor.</p>

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.

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 MEDSURGE contains

Active ingredient (main ingredient)	Sugammadex (as sodium salt)
Other ingredients (inactive ingredients)	hydrochloric acid, sodium hydroxide, and Water for Injections

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

What SUGAMMADEX MEDSURGE looks like

SUGAMMADEX MEDSURGE solution for injection is a clear and colourless to slightly yellow solution.

SUGAMMADEX MEDSURGE is available as

- 200 mg/2 mL pack of 10 vials
- 500 mg/5 mL pack of 10 vials

Who distributes SUGAMMADEX MEDSURGE

New Zealand Sponsor

Medsurge Pharma Limited

P O Box 331054

Takapuna

Auckland 0622

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Telephone: 0800 788 261

Website: <http://www.medsurgehc.com/>

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