

SUGAMMADEX-TEVA

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-TEVA?

SUGAMMADEX-TEVA contains the active ingredient sugammadex (as sodium). SUGAMMADEX-TEVA is used to speed up recovery of your muscles after an operation.

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

2. What should I know before I use SUGAMMADEX-TEVA?

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-TEVA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SUGAMMADEX-TEVA 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-TEVA?

SUGAMMADEX-TEVA is given as a single injection through an intravenous line. The doctor will work out the dose of SUGAMMADEX-TEVA you need based on your weight and how much muscle relaxant is still affecting you.

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

5. What should I know while using SUGAMMADEX-TEVA?

Driving or using machines	<ul style="list-style-type: none">Your doctor will tell you when it is safe
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	to drive and operate potentially dangerous machinery. As far as it is known, SUGAMMADEX-TEVA has no effect on alertness or concentration.
Storage	<ul style="list-style-type: none"> • SUGAMMADEX-TEVA is stored in the hospital according to the storage conditions on the pack.

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

6. Are there any side effects?

Like all medicines, SUGAMMADEX-TEVA can cause side effects, but not everyone gets them.

If these 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-TEVA

Solution for Injection

Active ingredient(s): sugammadex (as sodium)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SUGAMMADEX-TEVA. **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-TEVA.**

Where to find information in this leaflet:

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

1. Why am I using SUGAMMADEX-TEVA?

SUGAMMADEX-TEVA contains the active ingredient sugammadex (as sodium). SUGAMMADEX-TEVA belongs to a group of medicines called Selective Relaxant Binding Agents.

SUGAMMADEX-TEVA 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-TEVA is used to stop the muscle relaxants working. It does this by combining with rocuronium or vecuronium in your body.

SUGAMMADEX-TEVA 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-TEVA.

2. What should I know before I use SUGAMMADEX-TEVA?

Warnings

Do not use SUGAMMADEX-TEVA 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 or difficulty breathing
- swelling of the tongue and/or throat
- rash or red skin

Check with your doctor if you:

- have any other medical conditions including present or past kidney disease, diseases known to increase risk of bleeding, present or past liver disease and fluid retention (oedema)
- 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-TEVA if you are pregnant or breastfeeding.

Children

SUGAMMADEX-TEVA is not recommend for infants less than 2 years of age.

Laboratory tests

In general, SUGAMMADEX-TEVA 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.

SUGAMMADEX-TEVA may interfere with some medicines and affect how they work.

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

If you are taking the PILL the same day as SUGAMMADEX-TEVA 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.

Medicines that may reduce the effect of SUGAMMADEX-TEVA 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-TEVA.

4. How do I use SUGAMMADEX-TEVA?

How much to use

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

The doctor will work out the dose of SUGAMMADEX-TEVA 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-TEVA

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

5. What should I know while using SUGAMMADEX-TEVA?

Driving or using machines

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

Storage

SUGAMMADEX-TEVA 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, anaesthetist or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious 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	<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>

Less serious side effects	What to do
to move or cough at the end of the operation.	

Serious side effects

Serious side effects	What to do
<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. ● 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.</p> <p>If after your operation, you notice any side effects tell your doctor.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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-TEVA is administered. ● Complications during your procedure such as changes in heart rate, coughing or moving. ● Decreased blood pressure due to the procedure. 	

Tell your doctor, anaesthetist 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 OR Medsafe online at www.tga.gov.au/reporting-problems OR <https://nzphvc.otago.ac.nz/reporting/> By reporting side effects,

you can help provide more information on the safety of this medicine.

7. Product details

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

What SUGAMMADEX-TEVA contains

Active ingredient (main ingredient)	Sugammadex (as sodium) 200 mg or 500 mg
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.

What SUGAMMADEX-TEVA looks like

SUGAMMADEX-TEVA is a clear, colourless to slightly yellow-brown solution for injection.

SUGAMMADEX-TEVA is available as:

- 200 mg/2 mL pack of 10 vials (Aust R 375461)
- 500 mg/5 mL pack of 10 vials (Aust R 375460)

Not all strengths may be marketed

Who distributes SUGAMMADEX-TEVA

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Teva Pharma (New Zealand) Ltd

Auckland, New Zealand

This leaflet was prepared in March 2023.