

# SUGAMMADEX-TEVA

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## 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.

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### 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?**

<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Your doctor will tell you when it is safe</li></ul>
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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.
<b>Storage</b>	<ul style="list-style-type: none"> <li>• SUGAMMADEX-TEVA is stored in the hospital according to the storage conditions on the pack.</li> </ul>

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)

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## 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.

You may already have been given SUGAMMADEX-TEVA Injection. 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-TEVA.

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

Sugammadex-Teva is not addictive.

## **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 heart problems

- have kidney disease or have had it in the past. This is important because Sugammadex-Teva is removed from your body by the kidneys
- have any diseases known to give an increased risk of bleeding (disturbance of blood clotting) or anticoagulation medicine
- have liver disease or have had it in the past
- have fluid retention (oedema)
- have a history of airway or lung problems
- take any medicines for any other condition
- have allergies to any other medicines

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 recommended 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.

**Some medicines may interfere with SUGAMMADEX-TEVA and affect how it works.**

**Medicines that may reduce the effect of SUGAMMADEX-TEVA include:**

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

**SUGAMMADEX-TEVA 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-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.

**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**

**Be careful before you drive or use any machines or tools until you know how SUGAMMADEX-TEVA 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-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.

### Serious side effects

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="202 994 751 1099"><b>Signs and symptoms of lung problems:</b></p> <ul data-bbox="202 1137 775 2007" style="list-style-type: none"><li data-bbox="202 1137 775 1352">● Coughing, mild bucking, wheezing, feeling of choking, hoarse or strained voice</li><li data-bbox="202 1375 775 1653">● Airway difficulties that may include coughing or moving as if you are waking or taking a breath</li><li data-bbox="202 1675 775 2007">● Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems</li></ul>	<p data-bbox="809 994 1358 1272"><b>If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.</b></p> <p data-bbox="809 1339 1345 1496"><b>If after your operation, you notice any side effects tell your doctor.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="204 286 751 389"><b>Signs and symptoms of heart problems:</b></p> <ul data-bbox="204 427 783 1536" style="list-style-type: none"> <li data-bbox="204 427 667 591">● Decreased blood pressure due to the procedure</li> <li data-bbox="204 611 740 943">● Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUGAMMADEX-TEVA is administered</li> <li data-bbox="204 963 783 1417">● Abnormal heart rhythm, chest discomfort or pain, palpitations, fainting, shortness of breath, weakness, fatigue, dizziness, lightheadedness, bluish skin, sweating or nausea</li> <li data-bbox="204 1438 584 1536">● Abnormally fast heartbeat</li> </ul> <p data-bbox="204 1563 751 1666"><b>Signs and symptoms of allergic reactions:</b></p> <ul data-bbox="204 1704 759 2042" style="list-style-type: none"> <li data-bbox="204 1704 759 2042">● Allergic reactions such as a rash or red skin, swelling of the tongue and/or throat, shortness of breath, changes in blood pressure or</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>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> <p><b>Signs and symptoms of muscle problems:</b></p> <ul style="list-style-type: none"> <li>• Return of muscle relaxation after the operation.</li> </ul> <p><b>Signs and symptoms of problems in other organs:</b></p> <ul style="list-style-type: none"> <li>• Light anaesthesia – you may start to come out of a deep sleep and need more anaesthetic. This might cause you to move or cough at the end of the operation.</li> <li>• Complications during your procedure such as</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
changes in heart rate, coughing or moving.	

**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](http://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**

<b>Active ingredient (main ingredient)</b>	Sugammadex (as sodium) 200 mg or 500 mg
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<b>Other ingredients (inactive ingredients)</b>	Hydrochloric acid Sodium hydroxide Water for Injections
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**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 2026.