

# SUGAMMADEX ACCORD

## 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 Accord?

Sugammadex Accord contains the active ingredient sugammadex. Sugammadex belongs to a group of medicines called Selective Relaxant Binding Agents. It is used to speed up recovery of your muscles after an operation.

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

### 2. What should I know before I use Sugammadex Accord?

Do not use if you are allergic to sugammadex or have an allergy to any of the ingredients listed at the end of this leaflet.

**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'm given Sugammadex Accord?](#) in the full CMI.

### 3. What if I am taking other medicines?

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

See Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Sugammadex Accord?

Sugammadex Accord is an injection and will be given to you by your doctor.

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

### 5. What should I know while using Sugammadex Accord?

|                                  |   |
|----------------------------------|---|
| <b>Driving or using machines</b> | Be careful driving or operating machinery until you know how Sugammadex Accord 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 Accord has no effect on alertness or concentration. |
|----------------------------------|---|

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

### 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.

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

The serious side effects are:

- 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 airways (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 Accord is administered

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 ACCORD

Active ingredient: *sugammadex*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Sugammadex Accord. **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 Accord.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Sugammadex Accord?

**Sugammadex Accord contains the active ingredient sugammadex.** Sugammadex belongs to a group of medicines called Selective Relaxant Binding Agents. 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 Accord is used to stop the muscle relaxants working. It does this by combining with rocuronium or vecuronium in your body.**

**Sugammadex Accord 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.**

## 2. What should I know before I'm given Sugammadex Accord?

### Warnings

**Do not receive Sugammadex Accord if:**

- you are allergic to sugammadex or have an allergy to any of the ingredients listed at the end of this leaflet

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

**Check with your doctor if you have or have had:**

- an allergy to any other medicines, foods, preservatives or dyes
- kidney disease (this is important because Sugammadex Accord is removed from your body by the kidneys)
- liver disease
- any diseases known to give an increased risk of bleeding (disturbance of blood clotting).
- fluid retention (oedema)

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 Accord if you are pregnant or breast-feeding.

## 3. What if I am taking other medicines?

Tell your doctor 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 and Sugammadex Accord may interfere with each other.**

- toremifene (used to treat breast cancer)
- fusidic acid (an antibiotic)
- flucloxacillin (an antibiotic)
- Tell your doctor if you are using a hormonal contraceptive such as the "PILL", vaginal ring, implants or hormonal Intrauterine System (IUS)

Sugammadex Accord 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 Accord is about the same as missing one oral contraceptive Pill.

If you are taking the PILL the same day as Sugammadex Accord 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 Accord 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 Accord.**

#### 4. How is Sugammadex Accord given?

##### How much to use

Sugammadex Accord is given as an injection into your vein (intravenously) as a single injection. The doctor will work out the dose of Sugammadex Accord 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 Accord for children and adolescents between 2-17 years old is 2 mg per kg.

##### If you use too much Sugammadex Accord

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

#### 5. What should I know while using Sugammadex Accord?

##### Driving or using machines

**Be careful driving or operating machinery until you know how Sugammadex Accord 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 Accord has no effect on alertness or concentration.

##### Looking after your medicine

The hospital will store Sugammadex Accord under the correct conditions.

##### Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Sugammadex Accord that may be left over.

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.

#### Serious side effects

| Serious side effects  | What to do  |
|---|---|
| <ul style="list-style-type: none"><li>• cough</li><li>• airway difficulties that may include coughing or moving as if you are waking or taking a breath</li><li>• 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</li><li>• complications during your procedure such as changes in heart rate, coughing or moving</li><li>• decreased blood pressure due to the procedure</li><li>• 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</li><li>• shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems</li><li>• return of muscle relaxation after the operation</li><li>• severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when Sugammadex Accord is administered</li></ul> | <b>If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.</b> |

**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](http://www.tga.gov.au/reporting-problems). 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.

Sugammadex Accord is not addictive.

### What Sugammadex Accord contains

|   |   |
|---|---|
| <b>Active ingredient<br/>(main ingredient)</b>      | sugammadex  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | sodium hydroxide<br>hydrochloric acid<br>water for injections |

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

### What Sugammadex Accord looks like

Sugammadex Accord is a clear colourless to slightly yellow-brown solution supplied in a vial in packs of 10.

(200 mg/2 mL: AUST R 372777, 500 mg/5 mL: AUST R 372778).

### Who distributes Sugammadex Accord

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne, VIC, 3000  
Australia

This leaflet was prepared in September 2022.