

Sugammadex ARX

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 ARX?

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

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

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

You should not be given Sugammadex ARX if you have ever had an allergic reaction to Sugammadex ARX 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?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sugammadex ARX 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 is Sugammadex ARX given?

- Sugammadex ARX is given as a single injection through an intravenous line.
- Your doctor will work out the dose of Sugammadex ARX you need.

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

5. What should I know after being given Sugammadex ARX?

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 ARX has no effect on alertness or concentration.
Storage	<ul style="list-style-type: none">• Sugammadex ARX is stored in the hospital according to the storage conditions on the pack.

For more information, see Section [5. What should I know after being given Sugammadex ARX?](#) 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 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 ARX[®]

Active ingredient(s): *Sugammadex*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Sugammadex ARX?

Sugammadex ARX contains the active ingredient sugammadex. Sugammadex belongs to a group of medicines called Selective Relaxant Binding Agents.

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

Sugammadex ARX 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.

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

Sugammadex ARX is not addictive.

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

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

Warnings

You must not be given Sugammadex ARX if:

- you are allergic to sugammadex, or any of the ingredients listed at the end of this leaflet.

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 problem.
- have kidney disease or have had it in the past. This is important because Sugammadex ARX 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 medication.
- 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.
- have allergies to any other substances, such as foods, preservatives or dyes.

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 ARX if you are pregnant or breast-feeding.

Use in children

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

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 may interfere with Sugammadex ARX and affect how it works.

Medicines that may reduce the effect of Sugammadex ARX include:

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

Tell your doctor if you are taking or have recently taken these medicines.

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

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

If you are taking the PILL the same day as Sugammadex ARX 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 contraception method (such as a condom) for the next 7 days.

Laboratory tests: In general, Sugammadex ARX 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 if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sugammadex ARX.

4. How is Sugammadex ARX given?

Sugammadex ARX is given as a single injection through an intravenous line.

How much you are given

The doctor will work out the dose of Sugammadex ARX 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 ARX

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much Sugammadex

ARX. Even if this happens, it is unlikely to cause any problems.

5. What should I know after being given Sugammadex ARX?

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 ARX has no effect on alertness or concentration.

Looking after your medicine

Sugammadex ARX 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 if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none"> • Coughing, mild bucking, wheezing, feeling of choking, hoarse or strained voice. • 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 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 	<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>

AUST R 371180 (500 mg/5 mL)

Who distributes Sugammadex ARX

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel street
Cremorne, VIC 3121

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<p>muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems.</p> <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 ARX is administered.• Abnormal heart rhythm, chest discomfort or pain, palpitations, fainting, shortness of breath, weakness, fatigue, dizziness, lightheadedness, bluish skin, sweating or nausea.• Abnormally fast heartbeat.	
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Tell your doctor 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. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available in the hospital.

What Sugammadex ARX contains

Active ingredient (main ingredient)	Sugammadex (200 mg or 500 mg)
Other ingredients (inactive ingredients)	Hydrochloric acid and/or Sodium hydroxide for pH adjustment and Water for Injection.

You must not be given this medicine if you are allergic to any of these ingredients.

What Sugammadex ARX looks like

Sugammadex ARX is a clear and colourless to slightly yellow solution for injection.

Sugammadex ARX is available as

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

AUST R 356510 (200 mg/2 mL)