

SUGAMMADEX VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

1. Why am I given SUGAMMADEX VIATRIS?

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

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

2. What should I know before I am given SUGAMMADEX VIATRIS?

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

You must not be given SUGAMMADEX VIATRIS if you have ever had an allergic reaction to sugammadex or any of the ingredients listed at the end of the CMI.

For more information, see Section [2. What should I know before I am given SUGAMMADEX VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SUGAMMADEX VIATRIS 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 VIATRIS given?

The doctor will work out the dose of SUGAMMADEX VIATRIS you need based on your weight and 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 VIATRIS for children and adolescents between 2 - 17 years old is 2 mg per kg.

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

5. What should I know while given SUGAMMADEX VIATRIS?

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 VIATRIS has no effect on alertness or concentration.
Looking after the medicine	<ul style="list-style-type: none">• SUGAMMADEX VIATRIS is stored in the hospital according to the storage conditions on the pack.

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

6. Are there any side effects?

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

If the 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 VIATRIS

Active ingredient(s): *sugammadex (as sodium)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SUGAMMADEX VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about SUGAMMADEX VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I given SUGAMMADEX VIATRIS?

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

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

SUGAMMADEX VIATRIS 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 VIATRIS.

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

SUGAMMADEX VIATRIS is not addictive.

2. What should I know before I am given SUGAMMADEX VIATRIS?

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

Warnings

Do not use SUGAMMADEX VIATRIS 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 and rash or red skin.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- Have kidney disease or have had it in the past. This is important because SUGAMMADEX VIATRIS is removed from your body through 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.
- Have fluid retention (oedema).
- Have allergies to any other medicines and 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 for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell 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 VIATRIS if you pregnant or breast-feeding.

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

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 VIATRIS and affect how it works.

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

- 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 VIATRIS 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 VIATRIS is about the same as missing one oral contraceptive pill.

If you are taking the PILL the same day as SUGAMMADEX VIATRIS 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 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 VIATRIS 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 VIATRIS.

4. How is SUGAMMADEX VIATRIS given?

How much is given

- SUGAMMADEX VIATRIS is given as a single injection through an intravenous line.
- The doctor will work out the dose of SUGAMMADEX VIATRIS 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.

If you are given too much SUGAMMADEX VIATRIS

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

5. What should I know while given SUGAMMADEX VIATRIS?

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 VIATRIS has no effect on alertness or concentration.

Looking after your medicine

- SUGAMMADEX VIATRIS is stored in hospital according to the storage conditions on the pack.

6. Are there any side effects?

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

Side effects

Side effects	What to do
Signs and symptoms of lung problems: <ul style="list-style-type: none"> • Cough. • Airway difficulties that may include coughing or moving as if you are waking or taking a breath. 	If these side effects occur while you are under anaesthetic, they will be

Side effects	What to do
<ul style="list-style-type: none"> • Shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems. Signs and symptoms of heart problems <ul style="list-style-type: none"> • Decreased blood pressure due to the procedure. • Severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when SUGAMMADEX VIATRIS is administered. Signs and symptoms of allergic reactions <ul style="list-style-type: none"> • 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. Signs and symptoms of muscle problems <ul style="list-style-type: none"> • Return of muscle relaxation after the operation. Signs and symptoms of problems in other organs <ul style="list-style-type: none"> • 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. • Complication during your procedure such as changes in heart rate, coughing or moving. 	seen and treated by your anaesthetist.

If after your operation, you notice any side effects tell your doctor.

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. 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

What SUGAMMADEX VIATRIS contains

Active ingredient (main ingredient)	Sugammadex (as sodium)
Other ingredients (inactive ingredients)	Hydrochloric acid Sodium hydroxide Water for injections

What SUGAMMADEX VIATRIS looks like

SUGAMMADEX VIATRIS is a clear and colourless to slightly yellow solution (AUST R 377048).

SUGAMMADEX VIATRIS is available as

- 200 mg/2 mL pack of 10 vials

Who distributes SUGAMMADEX VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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