

Package leaflet: Information for the user

Sugammadex Teva 100 mg/ml solution for injection sugammadex

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your anaesthetist or doctor.
- If you get any side effects, talk to your anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sugammadex Teva is and what it is used for
2. What you need to know before Sugammadex Teva is given
3. How Sugammadex Teva is given
4. Possible side effects
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6. Contents of the pack and other information

1. What Sugammadex Teva is and what it is used for

What Sugammadex Teva is

Sugammadex Teva contains the active substance sugammadex. Sugammadex Teva is considered to be a *Selective Relaxant Binding Agent* since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

What Sugammadex Teva is used for

When you have some types of operations, your muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic you are given includes medicines to make your muscles relax. These are called *muscle relaxants*, and examples include rocuronium bromide and vecuronium bromide. Because these medicines also make your breathing muscles relax, you need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again.

Sugammadex Teva is used to speed up the recovery of your muscles after an operation to allow you to breathe on your own again earlier. It does this by combining with the rocuronium bromide or vecuronium bromide in your body. It can be used in adults whenever rocuronium bromide or vecuronium bromide is used and in children and adolescents (aged 2 to 17 years) when rocuronium bromide is used for a moderate level of relaxation.

2. What you need to know before Sugammadex Teva is given

You should not be given Sugammadex Teva

- if you are allergic to sugammadex or any of the other ingredients of this medicine (listed in section 6).

→ Tell your anaesthetist if this applies to you.

Warnings and precautions

Talk to your anaesthetist before Sugammadex Teva is given if you:

- have kidney disease or had it in the past. This is important as Sugammadex Teva is removed from your body by the kidneys.
- have liver disease or have had it in the past
- have fluid retention (oedema)

- have diseases which are known to give an increased risk of bleeding (disturbances of blood clotting) or anticoagulation medication.

Children and adolescents

This medicine is not recommended for infants less than 2 years of age.

Other medicines and Sugammadex Teva

→ Tell your anaesthetist if you are taking, have recently taken or might take any other medicines. Sugammadex Teva may affect other medicines or be affected by them.

Some medicines reduce the effect of Sugammadex Teva

→ It is especially important that you tell your anaesthetist if you have recently taken:

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

Sugammadex Teva can affect hormonal contraceptives

- Sugammadex Teva can make hormonal contraceptives - including the 'Pill', vaginal ring, implants or a hormonal IntraUterine System (IUS) - less effective because it reduces how much you get of the progestogen hormone. 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** on the same day as Sugammadex Teva is given to you, follow the instructions for a missed dose in the Pill's package leaflet.
 - If you are using **other** hormonal contraceptives (for example a vaginal ring, implant or IUS) you should use an additional non-hormonal contraceptive method (such as a condom) for the next 7 days and follow the advice in the package leaflet.

Effects on blood 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. Talk to your doctor if your progesterone levels need to be tested on the same day you receive Sugammadex Teva.

Pregnancy and breast-feeding

→ Tell your anaesthetist if you are pregnant or might be pregnant or if you are breast-feeding. You may still be given Sugammadex Teva, but you need to discuss it first. It is not known whether sugammadex can pass into breast milk. Your anaesthetist will help you decide whether to stop breast-feeding, or whether to abstain from sugammadex therapy, considering the benefit of breast-feeding to the baby and the benefit of Sugammadex Teva to the mother.

Driving and using machines

Sugammadex Teva has no known influence on your ability to drive and use machines.

Sugammadex Teva contains sodium

This medicine contains up to 9.7 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Sugammadex Teva is given

Sugammadex Teva will be given to you by your anaesthetist, or under the care of your anaesthetist.

The dose

Your anaesthetist will work out the dose of Sugammadex Teva you need based on:

- your weight
- how much the muscle relaxant medicine is still affecting you.

The usual dose is 2-4 mg per kg body weight for adults and for children and adolescents between 2-17 years old. A dose of 16 mg/kg can be used in adults if urgent recovery from muscle relaxation is needed.

How Sugammadex Teva is given

Sugammadex Teva will be given to you by your anaesthetist. It is given as a single injection through an intravenous line.

If more Sugammadex Teva is given to you than recommended

As your anaesthetist will be monitoring your condition carefully, it is unlikely that you will be given too much Sugammadex Teva. But even if this happens, it is unlikely to cause any problems.

If you have any further questions on the use of this medicine, ask your anaesthetist or other doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If these side effects occur while you are under anaesthesia, they will be seen and treated by your anaesthetist.

Common side effects (may affect up to 1 in 10 people)

- 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, so need more anaesthesia. 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 surgical procedure.

Uncommon side effects (may affect up to 1 in 100 people)

- shortness of breath due to muscle cramps of the airways (bronchospasm) occurred in patients with a history of lung problems
- allergic (drug hypersensitivity) reactions - such as a rash, red skin, swelling of your tongue and/or throat, shortness of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure. Severe allergic or allergic-like reactions can be life threatening. Allergic reactions were reported more commonly in healthy, conscious volunteers
- return of muscle relaxation after the operation.

Frequency not known

- severe slowing of the heart and slowing of the heart up to cardiac arrest may occur when Sugammadex Teva is administered.

Reporting of side effects

If you get any side effects, talk to your anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sugammadex Teva

Storage will be handled by healthcare professionals.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not freeze. Keep the vial in the outer carton in order to protect from light.

After first opening and dilution, store at 2 to 8°C protected from light and use within 24 hours.

6. Contents of the pack and other information

What Sugammadex Teva contains

- The active substance is sugammadex.
1 ml solution for injection contains sugammadex sodium equivalent to 100 mg sugammadex.
Each vial of 2 ml contains sugammadex sodium equivalent to 200 mg sugammadex.
Each vial of 5 ml contains sugammadex sodium equivalent to 500 mg sugammadex.
- The other ingredients are water for injections, hydrochloric acid and/or sodium hydroxide.

What Sugammadex Teva looks like and contents of the pack

Sugammadex Teva is a clear and colourless to slightly yellow-brown solution for injection. It comes in two different pack sizes, containing either 10 vials with 2 ml or 10 vials with 5 ml solution for injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva B.V., Swensweg 5, 2031 GA Haarlem, Netherlands

Manufacturer

PLIVA Croatia Ltd., Prilaz baruna Filipovića 25, Zagreb, 10000, Croatia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Croatia:	Sugamadeks Teva 100 mg/ml otopina za injekciju
Austria:	Sugammadex ratiopharm 100 mg/ml Injektionslösung
Belgium:	Sugammadex Teva 100 mg/ml oplossing voor injectie / solution injectable/Injektionslösung
Germany:	Sugammadex-ratiopharm 100 mg/ml Injektionslösung
Denmark:	Sugammadex Teva
Spain:	Sugammadex Teva 100 mg/ml solución inyectable EFG
France:	SUGAMMADEX TEVA 100mg/ml, solution injectable
Hungary:	Sugammadex Teva 100mg/ml oldatos injekció
Ireland:	Sugammadex Teva 100 mg/ml solution for injection
Italy:	Sugammadex Teva
Netherlands:	Sugammadex Teva 100 mg/ml, oplossing voor injectie
Norway:	Sugammadex Teva
Poland:	Sugammadex Teva
Portugal:	Sugamadex Teva
Romania:	Sugammadex TEVA 100 mg/ml soluție injectabilă
Sweden:	Sugammadex Teva
Slovenia:	Sugamadeks Teva 100 mg/ml raztopina za injiciranje

This leaflet was last revised in May 2022

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The following information is intended for healthcare professionals only:

For detailed information refer to the Summary of Product Characteristics of Sugammadex Teva