

## Package leaflet: Information for the user

### Sugammadex Rowex 100 mg/ml solution for injection sugammadex

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

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

#### **What is in this leaflet**

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

#### **1. What Sugammadex Rowex is and what it is used for**

##### **What Sugammadex Rowex is**

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

##### **What Sugammadex Rowex 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 Rowex 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 Rowex is given**

##### **You should not be given Sugammadex Rowex**

- 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 Rowex is given

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

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

Some medicines reduce the effect of Sugammadex Rowex

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 Rowex can affect hormonal contraceptives**

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

- If you are taking the **Pill** on the same day as Sugammadex Rowex 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.

### **Effect on blood tests**

In general, Sugammadex Rowex 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 Rowex.

### **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 Rowex, 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 Rowex to the mother.

### **Driving and using machines**

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

### **Sugammadex Rowex contains sodium**

The medicine contains up to 9.7 mg sodium (main component of cooking/table salt) in each ml.

2 ml vial of medicine contains less than 23 mg sodium, that is to say essentially 'sodium-free'.  
5 ml vial of the medicine contains up to 48.5 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How Sugammadex Rowex is given**

Sugammadex Rowex 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 Rowex 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 Rowex is given**

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

#### **If more Sugammadex Rowex 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 Rowex. 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 Rowex 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 national reporting system: HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store Sugammadex Rowex**

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 vial and carton 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

After first opening chemical and physical in-use stability has been demonstrated for 96 hours at 2°C-8°C with light protection and at 20°C- 25°C without light protection (withdrawal of solution with a needle or injection spike).

Additionally, solution for injection, withdrawn as described above, is chemically and physically stable in polypropylene syringes for 96 hours at 2°C-8°C with light protection and at 20°C- 25°C without light protection..

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless opening and withdrawal has taken place in controlled and validated aseptic conditions.

#### After dilution

After dilution, chemical and physical in-use stability has been demonstrated for 48 hours at 2°C to 25°C. From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Sugammadex Rowex contains**

- The active substance is sugammadex.

Each ml of 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 injection, hydrochloric acid, concentrated and/or sodium hydroxide.

#### **What Sugammadex Rowex looks like and content of the pack**

Sugammadex Rowex is a solution for injection. It is a clear and colourless to slightly yellow-brown solution, practically free from visible particles contained in colourless type I glass vials with a grey rubber stopper.

It comes in three different pack sizes, containing either 10 vials with 2 ml or 10 vials with 5 ml or or 1 vial with 5 ml solution for injection. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

##### **Manufacturer**

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

#### **This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

|                 |  |
|-----------------|--|
| Austria         | Sugammadex Sandoz 100 mg/ml - Injektionslösung       |
| Belgium         | Sugammadex Sandoz 100 mg/ml oplossing voor injectie  |
| Croatia         | Sugamadeks Sandoz 100 mg/ml otopina za injekciju     |
| Czechia         | Sugammadex Sandoz                                    |
| Finland         | Sugammadex Sandoz 100 mg/ml injektioneste, liuos     |
| Germany         | Sugammadex HEXAL 100 mg/ml Injektionslösung          |
| Greece          | Sugammadex/Sandoz 100 mg/mL ενέσιμο διάλυμα          |
| Ireland         | Sugammadex Rowex 100 mg/ml solution for injection    |
| Italy           | Sugammadex Sandoz                                    |
| Poland          | Sugammadex Sandoz                                    |
| Portugal        | Sugamadex Sandoz                                     |
| Romania         | Sugammadex Sandoz 100 mg/ml soluție injectabilă      |
| Slovenia        | Sugamadeks Sandoz 100 mg/ml raztopina za injiciranje |
| Spain           | Sugammadex Sandoz 100 mg/ml solución inyectable EFG  |
| The Netherlands | Sugammadex Sandoz 100 mg/ml, oplossing voor injectie |
| United Kingdom  | Sugammadex Sandoz 100mg/ml solution for injection    |

**This leaflet was last revised in 12/2022.**

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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 Rowex.