

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rocuronium bromide 10 mg/ml solution for injection/infusion

Rocuronium bromide

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT ROCURONIUM BROMIDE IS AND WHAT IT IS USED FOR

Rocuronium bromide belongs to a group of medicines called muscle relaxants.

Normally the nerves send messages to the muscles by impulses. Rocuronium bromide acts by blocking these impulses so that the muscles become relaxed.

When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

Rocuronium bromide may also be used if you are having anaesthesia to ease the insertion of a tube into your trachea (windpipe) for artificial ventilation (mechanical assistance of breathing).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ROCURONIUM BROMIDE

Do not use Rocuronium bromide

- If you are allergic (hypersensitive) to rocuronium or bromide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Rocuronium bromide:

- If you are **allergic** to any muscle relaxant
- If you have a **kidney**, a **liver** or a **biliary disease**
- If you have a **heart disease** or a disease affecting your **blood circulation**
- If you have an **oedema** (e.g. in the ankle area)
- If you have a **disease affecting the nerves and muscles** (neuromuscular diseases, e.g. polio (poliomyelitis), myasthenia gravis, Eaton-Lambert syndrome)
- If you ever **developed a too low body temperature during an anaesthesia** (hypothermia)

- If you ever developed a **severe fever** (malignant hyperthermia) **during an anaesthesia**
- If you have **fever**
- If you have a **low calcium level** in the blood (hypocalcaemia), (caused for example by massive transfusions)
- If you have a **low potassium level** in the blood (hypokalaemia), (caused for example by severe vomiting, diarrhoea or diuretic therapy)
- If you have a **high magnesium level** in the blood (hypermagnesaemia)
- If you have a **low level of proteins** in the blood (hypoproteinaemia)
- If you suffer from **dehydration**
- If you have **an increased amount of acids** in the blood (acidosis)
- If you have **an increased amount of carbon dioxide** in the blood (hypercapnia)
- If you tend to **overbreathing** (hyperventilation). Overbreathing leads to too little carbon dioxide in the blood (alkalosis)
- If you suffer from an **excessive loss of weight** (cachexia)
- If you are **overweight** or **elderly**
- If you have **burns**

Other medicines and Rocuronium bromide

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription such as:

- **antibiotics**
- **anti-depressants**: medicines used to treat depression (e.g. MAO inhibitors)
- medicines used for the treatment of **heart diseases** or **high blood pressure** (e.g. quinidine, calcium channel blocking agents, adrenergic blocking agents (e.g. beta blockers))
- **diuretics** or **water pills** (medicines which increase the amount of urine)
- some laxatives such as **magnesium salts**
- quinine (used to treat pain and infections)
- medicines used for **epilepsy treatment** (e.g. phenytoin, carbamazepine)
- corticosteroids
- medicines used for the treatment of **myasthenia gravis** (neostigmine, pyridostigmin)
- **vitamin B₁** (thiamine)
- **azathioprin** (used for transplant rejection prevention and treatment of auto-immune diseases)
- **theophylline** (used for the treatment of asthma)
- **noradrenaline** (a hormone which impacts blood pressure and other body functions)
- **potassium chloride**
- **calcium chloride**
- medicines used for the treatment or prevention of a virus infection (protease inhibitors)

Please note:

You may be given other medicines during the procedure which can influence the effects of rocuronium. These include certain anaesthetics (e.g. local anaesthetics, inhalational anaesthetics), other muscle relaxants, protamines which reverse the anticoagulant effect (prevention of blood clots) of heparin. Your doctor will take this into account when he is deciding the correct dose of rocuronium for you.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before this medicine is administered to you.

Pregnancy

Safe use of rocuronium bromide in pregnant women has not been established. Rocuronium bromide should only be administered to a pregnant woman if the attending physician considers this necessary despite potential risks.

Cesarean section

Rocuronium bromide has been shown to be safe in patients undergoing Cesarean section

Breast-feeding

No data are available on the use of Rocuronium bromide in breast-feeding mothers. Rocuronium bromide should only be given to breast-feeding mothers if the attending physician deems this necessary after weighing the risks and benefits.

Driving and using machines

Rocuronium bromide has a major influence on the ability to drive and use machines.

Therefore, it is not recommended to drive a vehicle or use potentially dangerous machines during the first 24 hours.

Your doctor should advise you when you can start driving and using machines again. You should always be accompanied home by a responsible adult after your treatment.

Important information about some of the ingredients of Rocuronium

This medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. essentially sodium free.

3. HOW TO USE ROCURONIUM BROMIDE

This medicine should only be administered by, or under the supervision of, experienced clinicians familiar with anaesthetic techniques.

Dosage

Rocuronium bromide is given to you intravenously either as a single injection or as a continuous infusion (over a longer period of time) into a vein.

The usual dose is 0.6 mg per kg body weight and its effect will last 30 to 40 minutes. During the surgery the effect of Rocuronium is controlled continuously.

If necessary, additional doses could be administered to you. The dose is adjusted to your needs by your anaesthetist. It depends on many factors, such as drug interactions (their cross activity), taking into consideration the estimated length of surgery as well as your age and clinical condition.

This medicine is for single use only. Any unused solution for injection/infusion should be discarded.

If you use more Rocuronium bromide than you should

Your anaesthetist will carefully monitor you when you are under medication of Rocuronium bromide, therefore it is unlikely that you will be given too much Rocuronium bromide. If it happens, your anaesthetist will make sure that anaesthesia and artificial ventilation will be continued until you breathe on your own.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rocuronium bromide can cause side effects, although not everybody gets them.

Hypersensitivity reactions (allergic reactions) are rare but may be life-threatening. A hypersensitivity reaction may include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. Please inform your doctor or nurse immediately if one or more of these reactions occur.

Uncommon/rare (may affect up to 1 in 1,000 patients):

- Increase in heart rate
- Lowering of blood pressure

- Drug is too effective or not effective enough
- Drug works for longer than expected
- Pain at the injection site

Very rare (may affect less than 1 in 10,000 patients):

- Increased level of histamine in the blood
- Wheezing (bronchospasm)
- Itching or rash
- Widespread, severe rash (exanthema)
- Welts (angioedema)
- Hives (urticaria)
- Loss of movement (paralysis)
- Failure of circulation (circulatory collapse and shock)
- Anaphylactic reaction/shock (a life-threatening allergic reaction)
- Muscle weakness

Not known (frequency cannot be estimated from the available data):

- Severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction)
- Breathing (respiratory) failure
- Stop breathing (apnoea)

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via:

UK: the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: 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 ROCURONIUM BROMIDE

Keep out of the sight and reach of children.

Do not use Rocuronium bromide after the expiry date which is stated on the ampoule/vial label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C).

Do not freeze.

Keep the ampoule/vial in the outer carton in order to protect from light.

Rocuronium bromide may also be stored outside the refrigerator at a temperature of up to 25°C for a maximum of 12 weeks.

The solution should be used immediately after opening the ampoule/vial.

In-use shelf life of diluted medicinal product:

After dilution with infusion fluids (see section 6.6), chemical and physical in-use stability has been demonstrated for 24 hours at 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/administrator and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use Rocuronium bromide if you notice that the solution is not clear and not free from particles.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rocuronium bromide contains:

The active substance is: rocuronium bromide.

Each ml of solution of Rocuronium bromide injection/infusion contains 10 mg rocuronium bromide.

Each ampoule/vial with 5 ml contains 50 mg rocuronium bromide.

Each ampoule/vial with 10 ml contains 100 mg rocuronium bromide.

The other ingredients are:

Sodium acetate trihydrate, Sodium chloride, Acetic acid 99% (for pH adjustment), Acetic acid 30% (for pH adjustment), Water for injections, Sodium hydroxide (for pH adjustment).

What Rocuronium bromide looks like and the contents of the pack

Rocuronium 10 mg/ml solution for injection/infusion is a clear, colourless up to pale brown-yellowish solution.

Ampoules/Vials of 5 and 10 ml

Pack sizes:

10x 5 ml, 12x 5 ml, (6x 10) x 5 ml,

10x 10 ml, (2x 10) x 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Ibigen Srl,

Via Fossignano 2,

04011 Aprilia (LT),

Italy.

Manufacturer:

Solpharm Pharmazeutische Erzeugnisse GmbH.,

Industriestrasse 3,

34212 Melsungen,

Germany.

This leaflet was last revised in 03/2021

The following information is intended for medical or healthcare professionals only

Single use only.

Discard any unused solution.

The solution should be used immediately after opening the ampoule/vial.

Rocuronium bromide has been shown to be compatible with: sodium chloride 9 mg/ml (0.9%) solution, glucose 50 mg/ml (5%) solution, glucose 33 mg/ml (3.3 %) in sodium chloride 3 mg/ml (0.3%) solution, water for injections and Lactated Ringers.

Rocuronium bromide must not be mixed with other medicinal products except those mentioned above

Physical incompatibility has been documented for Rocuronium bromide when added to solutions containing the following active substances: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, intralipid, methohexital, methylprednisolone, prednisolone sodium succinate, thiopental, trimethoprim and vancomycin.

If Rocuronium bromide is administered via the same infusion line that is also used for other medicinal products, it is important that this infusion line is adequately flushed (e.g. with sodium chloride 9 mg/ml (0.9% w/v) solution) between administration of Rocuronium bromide and medicinal products for which incompatibility with Rocuronium bromide has been demonstrated or for which compatibility with Rocuronium bromide has not been established.