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 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 other 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 ROCURONIUM BROMIDE IS AND WHAT IT IS USED FOR

Rocuronium bromide is one of a group of drugs called *muscle relaxants*.
Muscle relaxants are used during an operation as part of the general anaesthetic. When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation. Normally the nerves send messages called *impulses* to your muscles. Rocuronium bromide acts by blocking these impulses so that the muscles relax. Because the breathing muscles also relax, you will need help to breathe (*artificial ventilation*) during and after your operation until you can breathe on your own again. During the operation your anaesthetist will keep a check on the effect of the muscle relaxant and if necessary will give you some more. At the end of surgery, the effects of the drug are allowed to wear off and you can start breathing on your own. Sometimes the anaesthetist will give you another drug to help speed this up.

Rocuronium bromide can also be used in Intensive Care Units for short term use to keep your muscles relaxed.

2. WHAT YOU NEED TO KNOW BEFORE ROCURONIUM BROMIDE IS GIVEN

You should not receive Rocuronium bromide
- if you are allergic (hypersensitive) to rocuronium, the bromide ion 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 you receive this medicine:
- if you are allergic to **muscle relaxants**
- if you have had **kidney, heart, liver** or **gall bladder** disease
- if you have had diseases affecting the **nerves** and **muscles** (e.g.*poliomyelitis*, *myasthenia gravis*)
- if you have **fluid retention** (*oedema*)

- if you have a history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles)

Some conditions may influence the effects of Rocuronium bromide— for example:
- low calcium levels in the blood
- low potassium levels in the blood
- high magnesium levels in the blood
- low levels of protein in the blood
- too much carbon dioxide in the blood (*acidosis*)
- loss of too much water from the body, for example by being sick, diarrhoea or sweating (*dehydration*)
- over-breathing leading to too little carbon dioxide in the blood (*alkalosis*)
- general ill-health
- being very overweight (*obesity*)
- burns
- very low body temperature (*hypothermia*)

If you have any of these conditions, your anaesthetist will take it into account when deciding the correct dose of Rocuronium bromide for you.

Children and elderly
Rocuronium bromide can be used in children (newborns and adolescents) and elderly but your anaesthetist should first assess your medical history.

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

Medicines which increase the effect of Rocuronium bromide:
- certain **antibiotics**
- certain medicines for **heart diseases** or **high blood pressure** (*water tablets, calcium channel blockers, beta-blockers and quinidine*)
- certain **anti-inflammatory** medicines (*corticosteroids*)
- **magnesium salts**
- certain medicines used for **bipolar disorder** (*lithium salts*)
- certain medicines used to treat **malaria** (*quinine*).
- certain medicines **used to make you sleep** during surgery (*anaesthetics*)
- certain medicines which cause **increased volume of urine** (*diuretics*)
- certain **local anaesthetics** (*lidocaine, bupivacaine*)
- certain medicines for **epilepsy** during an operation (*phenytoin*)
- certain medicines used to **induce short-term muscle relaxation** in anaesthesia and intensive care (*suxamethonium*)

Medicines which decrease the effect of Rocuronium bromide:
- long term use of medicines for **epilepsy** *(phenytoin and carbamazepine)*
- certain **protease inhibitors** called gabexate and ulinastatin
- acetylcholinesterase inhibitors, medicines for the **treatment of myasthenia gravis** (*e.g. neostigmine, edrophonium, pyridostigmine*)
- **calcium chloride** and **potassium chloride**

In addition, you may be given other medicines before or during surgery which can alter the effects of rocuronium. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of Rocuronium bromide. Rocuronium may make certain anaesthetics work more quickly. Your anaesthetist will take this into account when deciding the correct dose of Rocuronium bromide 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 anaesthetist for advice before receiving this medicine.

Your anaesthetist may still give you Rocuronium bromide but you need to discuss it first. Rocuronium bromide may be given to you if you are having a Caesarean section.
Breastfeeding should be suspended 6 hours after use of this medicine.

Driving and using machines
Do not drive or use machines until advised it is safe to do so. Because Rocuronium bromide is given as part of a general anaesthetic, you may feel tired, weak or dizzy for some time afterwards. Your anaesthetist will be able to advise you on how long the effects are likely to last.

Rocuronium bromide contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial/ampoule, that is to say essentially "sodium free".

3. HOW ROCURONIUM BROMIDE IS GIVEN

Dose
Your anaesthetist will work out the dose of Rocuronium bromide you need based on:
- the type of anaesthetic
- the expected length of the operation
- other drugs you are taking
- your state of health

The normal dose is 0.6 mg per kg body weight and the effect will last 30 - 40 minutes.

How Rocuronium bromide is given
Rocuronium bromide will be given to you by your anaesthetist. Rocuronium bromide is given intravenously (into a vein), either as single injections or as a continuous infusion (a drip).

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

If more Rocuronium bromide 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 Rocuronium bromide. However, if it happens, your anaesthetist will keep you breathing artificially (on a ventilator) until you breathe on your own. You will be kept asleep while this takes place.

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 anaesthetic, they will be seen and treated by your anaesthetist.

Uncommon (may affect up to 1 in 100 people)
- Increase in heart rate
- Lowering of blood pressure
- The drug is too effective or not effective enough
- The drug works for longer than expected
- Pain near the site of injection

Very rare (may affect up to 1 in 10,000 people)

- Allergic (*hypersensitivity*) reactions (such as difficulty in breathing, collapse of the circulation and shock)
- Wheezing of the chest
- Muscle weakness
- Swelling, a rash or wheals or redness of the skin
- Long term muscle dysfunction usually observed when rocuronium bromide and anti-inflammatory medicines (corticosteroids are used in the Intensive Care Unit at the same time in critically ill patients (steroid myopathy)
- Airway complication of anaesthesia

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).
- Dilated pupils (mydriasis) or fixed pupils that do not change in size with light or other stimuli.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet,
→ Tell your anaesthetist or other doctor.

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:
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 ROCURONIUM BROMIDE IS STORED

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 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, 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 this medicine if you notice that the solution is not clear and not free from particles.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rocuronium bromide contains

The active substance is: rocuronium bromide.
Each ml of solution for 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 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:
10 x 5 ml, 12 x 5 ml, (6 x 10) x 5 ml
10 x 10 ml, (2 x 10) x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Ibigen Srl,
Via Fossignano 2,
04011 Aprilia (LT),
Italy.

Manufacturer:
Solupharm Pharmazeutische Erzeugnisse GmbH.,
Industriestrasse 3,
34212 Melsungen,
Germany.

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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.