Package leaflet: Information for the patient

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 anaesthetist.
- If you get any side effects, talk to your doctor or anaesthetist. 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 belongs to a group of medicines called muscle relaxants.
Under normal circumstances your 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.

In *adults and children,* if you are under general anaesthesia*,* Rocuronium Bromide may be used to ease the insertion of a tube into your windpipe (trachea), to help with mechanical assistance of breathing and to ensure that your muscles are relaxed during surgery.

If you are an *adult* your doctor may also use this medicine for a short time as an additional medicine in the intensive care unit (ICU) (e.g. to ease the insertion of a tube into your windpipe and whilst you are receiving mechanical breathing). You may also receive this medicine whenever there is an emergency situation and you need to receive a tube into your windpipe very quickly.

2. What you need to know before you use Rocuronium Bromide

You should not receive Rocuronium Bromide:
- if you are allergic to rocuronium, the bromide ion or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or anaesthetist before using Rocuronium Bromide:

- if you are allergic to any muscle relaxants
- if you have had kidney, heart, liver or gall bladder disease
- if you have a heart disease or a disease affecting your blood circulation
- if you have had diseases affecting nerves and muscles, for example poliomyelitis, myasthenia gravis or Eaton-Lambert syndrome
- if you have fluid retention (oedema)
- if you have been told you have low levels of calcium (hypocalcaemia), potassium (hypokalaemia) or protein (hypoproteinaemia) in your blood
- if you have been told you have high levels of magnesium (hypermagnesaemia) or carbon dioxide (hypercapnia) in your blood
- if you have lost a lot of water from your body, for example by being sick, having diarrhoea, sweating
- if you are very overweight (obese)
- if you are elderly
- if you have a very low body temperature (hypothermia)
- if you have burns
- if you have an increased amount of acids in the blood (acidosis)
- if you suffer from an excessive loss of weight and poor physical condition (cachexia)

Children and the elderly

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

Other medicines and Rocuronium Bromide

Your doctor or anaesthetist needs to know if you are taking, have recently taken or might take any other medicines. This includes medicines or herbal products that you have bought without a prescription. Rocuronium Bromide may affect other medicines or be affected by them, in particular:

- certain anti-inflammatory medicines (corticosteroids) when used for a long time with Rocuronium Bromide, for example during intensive care
- certain antibiotics
- certain medicines for heart disease or high blood pressure (water tablets, calcium channel blockers, beta-blockers, alpha-blockers) and quinidine) magnesium salts which may be used as a laxative or in certain heart conditions eg pre-eclampsia
- lithium used for manic depressive illness (bipolar disorder)
- certain medicines for epilepsy
- calcium chloride and potassium chloride (medicines to change the levels of potassium or calcium in the blood)
- certain protease inhibitors called gabexate and ulinastatin (may be used for treating various viral infections or conditions such as pancreatitis)
- azathioprine (used after transplants and for treating of auto-immune diseases)
- theophylline (used for the treatment of asthma)
- medicines used for the treatment of myasthenia gravis (neostigmine, edrophonium, pyridostigmine)
- Aminopyridine derivatives(medicines used to treat Eaton-Lambert syndrome)

- quinine (used to treat malaria or night time leg cramps)

Please note in addition, you may be given other medicines before or during surgery which can alter the effects of Rocuronium Bromide. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of Rocuronium Bromide. Rocuronium Bromide 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, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or anaesthetist for advice before being given this medicine.
There is very limited information on the use of Rocuronium Bromide during human pregnancy or in breast-feeding women. Rocuronium Bromide should only be given to pregnant and nursing women when the doctor decides that the benefits outweigh the risks. Rocuronium Bromide may be given to you if you are having a Caesarean section.
There is no information available on the influence of this medicine on your fertility.

Driving and using machines
Rocuronium has a major influence on driving and using machines. Therefore, it is not recommended to drive a car or use potentially dangerous machines during the first 24 hours after full recovery from the effect of this medicine.

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.

Rocuronium Bromide contains sodium
Each millilitre (ml) of Rocuronium Bromide contains 1.56mg of sodium.
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

3. How to take Rocuronium Bromide

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 medicines 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).

If you are given more Rocuronium Bromide than you need
As your anaesthetist will be monitoring your condition carefully it is unlikely that you will be given too much Rocuronium Bromide. However, if this happens, your anaesthetist will keep you breathing artificially (on a ventilator) until you can breathe on your own. You will be kept asleep while this takes place.

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

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.

If any of the side effects get serious, talk to your doctor or anaesthetist.
The following side-effects have been reported at the approximate frequencies shown:
uncommon (≥1/1,000 to <1/100);
very rare (<1/10,000);

Uncommon side effects
(up to 1 in 100 users are affected)
- the medicine is too effective, or not effective enough
- the medicine works for longer than expected
- lowering of blood pressure
- increase in heart rate
- pain near the site of injection.

Very rare side effects
(less than 1 in 10,000 users are affected)
- allergic reactions (such as difficulty in breathing, collapse of the circulation and shock)
- wheezing of the chest
- muscle weakness
- swelling, a rash or redness of the skin
- problems with your airway

If you get any side effects, talk to your doctor or anaesthetist**.** This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system for

United Kingdom
Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard
or
Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@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 this medicine out of the sight and reach of children.

After first opening: Since Rocuronium Hospira does not contain a preservative, the solution should be used immediately after opening the vial.
After dilution with infusion fluids, chemical and physical in-use stability has been demonstrated for 72 hours at 30°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.

Store in a refrigerator (2°C – 8°C). Rocuronium Bromide can be stored outside of the refrigerator at a temperature of up to 30°C for a maximum of 12 weeks. The product should not be placed back into the refrigerator, once it has been kept outside. The storage period must not exceed the shelf-life.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP:.

Do not use Rocuronium Bromide if you notice that the solution is not clear and not free from particles.
Rocuronium Bromide should not be disposed of via wastewater or household waste. 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 millilitre (ml) contains 10 mg of rocuronium bromide
- Each 5ml vial contains 50 mg rocuronium bromide.
- Each 10ml vial contains 100 mg rocuronium bromide.
- The other ingredients are sodium acetate anhydrous, sodium chloride, acetic acid glacial, sodium hydroxide and water for injections.

Each 5 ml of Rocuronium Bromide contains 7.8 mg of sodium.
Each 10 ml of Rocuronium Bromide contains 15.6 mg of sodium.

What Rocuronium Bromide looks like and contents of the pack
Rocuronium Bromide is a colourless to yellow-orange solution for injection. It is available in vials containing 50 mg (10 vials per pack) or 100 mg (10 vials per pack) of rocuronium bromide.

Marketing Authorisation Holder and Manufacturer
Hospira UK Limited
Horizon,
Honey Lane,
Hurley
Maidenhead
SL6 6RJ
United Kingdom

Alternate Batch release site:

Hospira Enterprises B.V.
Randstad 2211,
1316 BN ALMERE
The Netherlands

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The following information is intended for healthcare professionals only:

Rocuronium Bromide 10 mg/ml Solution for Injection/Infusion

Please refer to the Summary of Product Characteristics for full prescribing information.

Like other neuromuscular blocking agents, rocuronium bromide should only be administered by, or under supervision of, experienced clinicians who are familiar with the action and use of these drugs.

Each vial of the 50 mg presentation contains 5ml of solution.
Each vial of the 100 mg presentation contains 10ml of solution.

Special precautions for storage
Unopened product: Store in a refrigerator (2-8^{o}C).

Rocuronium Bromide can be stored outside of the refrigerator at a temperature of up to 30^{o}C for a maximum of 12 weeks. The product should not be placed back into the refrigerator once it has been kept outside. The storage period must not exceed the shelf-life.

After first opening: Since Rocuronium Bromide does not contain preservative, the solution should be used immediately after opening the vial.

Diluted product: After dilution with Infusion fluids ('Special precautions for disposal and other handling'), chemical and physical in-use stability of the diluted product has been demonstrated for 72 hours at 30^{o}C.

From a microbiological point of view, the product should be used immediately after dilution. 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 to 8^{o}C.

Special precautions for disposal and other handling
The solution is to be visually inspected prior to use. Only clear solutions practically free from particles should be used.

Rocuronium bromide is administered intravenously as a bolus injection or continuous infusion.

Compatibility studies have been conducted with the following infusion fluids listed below.

Rocuronium Bromide in nominal concentrations of 0.5 mg/ml and 2.0 mg/ml is compatible with:
0.9% NaCl, 5% dextrose, 5% dextrose in 0.9% NaCl, sterile water for injection and lactated Ringer's solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities
Rocuronium bromide is physically incompatible with solutions of the following drugs: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, methohexital, methylprednisolone, prednislone sodium succinate, thiopental, trimethoprim and vancomycin. Furthermore rocuronium bromide is incompatible with Intralipid.

Rocuronium bromide should not be mixed with other drugs, except those listed in '*Special precautions for disposal and other handling'*.

If rocuronium bromide is administered via the same infusion line that is used for other drugs, it is important that this infusion line is adequately flushed (e.g. with 0.9% NaCl) between administration of rocuronium bromide and drugs for which incompatibility with rocuronium bromide has been demonstrated of for which compatibility with rocuronium bromide is not established.