107159

Package leaflet: Information for the user

Rocuronium bromide 10 mg / mL solution for injection in pre-filled syringe

rocuronium bromide

AGUETTANT

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.
- 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

Rocuronium bromide is a muscle relaxant used in adults and children from 2 years of age.
Muscle relaxants are used during a surgical procedure to assist in general anaesthesia. During a surgical procedure, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the surgical procedure. Normally, the nerves send signals to your muscles. This medicine can temporarily block these signals, thereby causing your muscles to relax. Because the muscles needed for breathing also relax, you will be given artificial respiration until you can breathe on your own again.
During the surgical procedure, the effect of the muscle relaxant will be constantly monitored and, if necessary, you will be given some more Rocuronium bromide. At the end of surgery, the effects of this medicine are allowed to wear off and you can start breathing on your own. Sometimes, another medicine will be given to speed up this recovery. This medicine can also be used in intensive care.

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

You must not be given Rocuronium bromide
- if you are allergic to rocuronium or any of the other ingredients of this medicine (listed in section 6).

Tell your doctor if this applies to you.

Warnings and precautions
Your medical history can affect the way in which you are given this medicine. Tell your doctor if you have, or have ever had, the following:
- an allergy to muscle relaxants
- poor kidney function (renal impairment) or kidney disease
- a cardiovascular disease
- oedema formation (fluid accumulation, e.g. on your ankles)
- liver disease, gallbladder or bile duct disease or poor liver function
- diseases affecting the nerves and muscles
- history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles).

Some medical conditions may affect the way this medicine works. For example:
- low potassium levels in the blood (hypokalaemia)
- high magnesium levels in the blood (hypermagnesaemia), e.g. when treating toxaemia of pregnancy with magnesium salts
- low calcium levels in the blood (hypocalcaemia)
- low protein levels in the blood (hypoproteinaemia)
- lack of fluids (dehydration)
- too much acid in the blood (acidosis)
- too much carbon dioxide in the blood (hypercapnia)
- general weak condition
- being overweight
- burns.

If any of these conditions apply to you, your doctor will take this into account when deciding on the right dose of this medicine for you.

Children and adolescents
This medicine can be used in children (2 - 11 years) and adolescents (12 - 17 years). However, maintenance dosage is not indicated in paediatric population under 12 years of age. Rocuronium bromide should not be given to children under 2 years because the subgraduation of the pre-filled syringe does not allow an accurate administration of the product in these populations.

Other medicines and Rocuronium bromide
Tell your doctor if you are using, have recently used or might use any other medicines. This will help your doctor determine the right dose of Rocuronium bromide for you.
The following medicines may influence the effect of Rocuronium bromide:
Medicines which increase the effect of Rocuronium bromide:
- certain anaesthetics
- medicine used to relax muscles (suxamethonium)
- certain medicines used to treat bacterial infections (antibiotics)
- certain medicines used for manic depressive illness (lithium)
- certain medicines for heart disease or high blood pressure (quinidine, calcium channel blockers, beta-blockers)
- certain medicines used to treat malaria (quinine)
- water tablets (diuretics)
- magnesium salts
- local anaesthetics (lidocaine and bupivacaine)
- short-term use of medicines for epilepsy (phenytoin), e.g. during surgery.

Medicines which decrease the effect of Rocuronium bromide:
- long-term use of corticosteroids (anti-inflammatory medicines) or medicines for epilepsy (phenytoin and carbamazepine)
- medicines for pancreatitis, problems with blood clotting and acute blood loss (protease inhibitors: gabexate, ulinastatin)
- calcium chloride, potassium chloride.

Medicines with a variable effect on Rocuronium bromide:
- other medicines used to relax the muscles.

Rocuronium bromide may influence the effect of the following medicines:
- the effect of local anaesthetics (lidocaine) may be increased.

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 for advice before you are given this medicine. There are very limited data on the use of rocuronium bromide during human pregnancy and no data on breast-feeding women. This medicine should only be given to pregnant and nursing women when the doctor decides that the benefits outweigh the risks.
This medicine may be given during Caesarean section.

Driving and using machines
Your doctor will tell you when you can resume driving or using dangerous machines after the use of this medicine.

Rocuronium bromide contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per pre-filled syringe, i.e essentially 'sodium free'.

The following information is intended for healthcare professionals only:

Aspect of the solution
The product should be inspected visually for particles and discolouration prior to administration. Only a clear colourless to pale brown-yellowish solution free from particles or precipitates should be used.

Incompatibilites of the solution
Rocuronium bromide is physically incompatible with solutions of the following medicinal products: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, methohexital, methylprednisolone, prednisolone sodium succinate, thiopental, trimethoprim and vancomycin.
Rocuronium bromide is also incompatible with intralipid.

Use of the pre-filled syringe
The content of an un-opened and un-damaged blister is sterile, and the blister must not be opened until the syringe is ready to be used.
The pre-filled syringe is for single patient only. Discard syringe after use. Do not reuse.
The pre-filled syringe is not suitable for accurate administration of the product in children younger than 2 years of age.
The product should not be used if the tamper evident seal on the syringe is broken.
Do not use this medicine if you notice visible signs of deterioration.

3. How to use Rocuronium bromide

Rocuronium bromide is not intended for self-administration. Rocuronium bromide will be injected as a solution into a vein.
It will be given by a single injection or via an infusion.

Dosage

Your doctor will determine the dosage of this medicine, based on:
- which type of anaesthetic is used
- the expected length of the surgical procedure
- other medicines you are using
- your age and state of health.

You will be given Rocuronium bromide before and/or during a surgical procedure by a healthcare professional. The normal dose is 0.6 mg rocuronium bromide per kilo of body weight and the effect lasts 30 to 40 minutes. During the procedure, it will be checked whether Rocuronium bromide is still working.
You will be given additional doses, if needed.

How Rocuronium bromide is given

Rocuronium bromide is not intended for self-administration. Rocuronium bromide will be injected as a solution into a vein.
It will be given by a single injection or via an infusion.

If you use more Rocuronium bromide than you should

As the medical staff will be monitoring your condition carefully, it is unlikely that you will be given too much Rocuronium bromide. However, if this happens, artificial respiration will be continued until you can breathe again on your own. It is possible to counter the effects of (too much) Rocuronium bromide and speed up your recovery, by giving you a medicine that counteracts the effects of this medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If these side effects occur during anaesthesia, they will be seen and treated by your doctor.
The following side effects may occur:

Uncommon/rare (may affect less than 1 in 100/1,000 people)
- rapid heartbeat (tachycardia)
- low blood pressure (hypotension)
- this medicine has no effect, or is too effective or not effective enough
- pain at the injection site
- redness or itching at the injection site
- prolongation of the muscle-relaxant effect of this medicine
- delayed recovery from anaesthesia.

Very rare: (may affect less than 1 in 10,000 people)
- allergic reactions, such as breathing difficulties, changes in blood pressure or heart rate, shock (sharp drop in blood pressure) due to insufficient circulating blood, or skin changes (e.g. fluid accumulation, redness or rash)
- excessive and prolonged contraction of the airway muscules causing breathing difficulty (bronchospasm)
- muscle weakness or paralysis
- sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching or rash, often as an allergic reaction (angioedema)
- fluid accumulation (oedema) in the face
- airway problems due to the anaesthetic
- rash, sometimes with severe itching and whealing (hives or urticaria)
- skin redness
- flushing.

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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly HPRA Pharmacovigilance 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 this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label, blister and carton.
Store in a refrigerator (2°C - 8°C).
Do not freeze.
Keep the pre-filled syringe in its unopened blister until use.
After opening, the medicinal product must be used immediately.
This medicine may be stored for a short period at temperatures not exceeding 30°C for a period of maximum 12 weeks. In all cases, once initially removed from refrigerated storage, the medicine should be discarded after 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 if you notice visible signs of deterioration.
Any pre-filled syringe, even partially used, should be discarded appropriately after use.
Do not throw away any medicines via wastewater. 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 Rocuronium bromide contains
- The active substance is rocuronium bromide.
  Each mL of solution contains 10 mg rocuronium bromide.
  Each 5 mL pre-filled syringe contains 50 mg rocuronium bromide (50 mg/5 mL).
- The other ingredients are sodium acetate trihydrate (E 262), sodium chloride, acetic acid glacial (E260) and water for injections.

What Rocuronium bromide looks like and contents of the pack

Rocuronium bromide is a clear colourless to pale brown-yellowish solution for injection or infusion, in a 5 mL polypropylene pre-filled syringe, with a graduated self-adhesive transparent label (sub - graduations of 0.2 mL from 0 until 5 mL).
Each pre-filled syringe is individually packed in a transparent blister pack.
Package size: Cardboard boxes of 10 pre-filled syringes.

Marketing Authorisation Holder and Manufacturer

Laboratoire Aguettant
1, rue Alexander Fleming
69007 Lyon - France

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

AT: Rocuroniumbromid Aguettant
FR, DE, IS, PL, RO: Rocuronium Aguettant
BE, DK, FI, LU, NO, SE: Rocuronium bromide Aguettant
IT: Rocuronio bromuro Aguettant
NL: Rocuroniumbromide Aguettant
PT: Brometo de Rocurónio Aguettant
ES: Rocuronio Aguettant
IE: Rocuronium bromide

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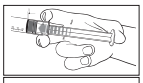
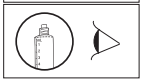
Please prepare the syringe carefully as follows

1) Withdraw the sterile pre-filled syringe from the blister.

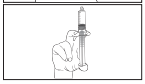


2) Push on the plunger to free the bung. The sterilisation process may have caused adhesion of the bung to the body of the syringe.

3) Twist off the end cap to break the seal. Do not touch the exposed luer connection in order to avoid contamination.



4) Check the syringe seal tip has been completely removed. If not, replace the cap and twist again.



5) Expel the air by gently pushing the plunger.

6) Connect the syringe to the vascular access device use a luer/luer lock system. Push the plunger slowly to inject the required volume. Administer the product according to the suitable administration route.

The pre-filled syringe is not suitable for syringe pump drivers. The pre-filled syringe is a ready to administer product, it is not suitable for dilution in an infusion pouch.Any syringe that has been damaged or has been handled without respecting the conditions of sterility must not be used.
Any unused product or waste material should be disposed of in accordance with local requirements.