Package leaflet: Information for the user

Rocuronium bromide Mylan 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Rocuronium bromide Mylan is and what it is used for

Rocuronium bromide Mylan is a muscle relaxant. Muscle relaxants are used during surgery as an aid to general anaesthesia. During surgery, your muscles must be completely relaxed, making it easier for the surgeon to operate. Normally, the nerves send signals to the muscles. Rocuronium bromide Mylan can temporarily block these signals so that your muscles will relax. As the muscles required to breathe also relax, you will be artificially ventilated until you can breathe independently again. During the operation, the effect of the muscle relaxant is constantly monitored, and, if necessary, more Rocuronium bromide Mylan is administered. At the end of the operation, time is allowed for Rocuronium bromide Mylan to wear off and for you to start breathing on your own again. Sometimes another medicine is administered to speed up this recovery. Rocuronium bromide Mylan can also be used in intensive care.

Children and adolescents
This medicine may be given to paediatric patients aged 0 to <18 years (term neonates to adolescents), as an adjunct to general anaesthesia to ease the insertion of a tube into the trachea (windpipe) of your child for artificial ventilation (mechanical assistance of breathing) and to relax the muscles.

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

Do not use Rocuronium bromide Mylan:

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

Tell your doctor if this applies to you.

Warning and precautions

Your medical history may have an effect on the manner in which Rocuronium bromide Mylan is given to you. Tell your doctor if you have or have had any of the following:
- – an allergy to muscle relaxants
- – impaired kidney function (renal insufficiency) or kidney disease
- – any heart or vascular disease
- – oedema (fluid retention at the ankles, for example)
- – any liver, gall bladder or biliary tract disorder or impaired liver function
- any disease affecting the nerves and muscles
- – a previous history of malignant hyperthermia (sudden fever with rapid heart rate, rapid breathing and muscle stiffness, muscle pain and/or muscle weakness).

Some medical conditions may affect the manner in which Rocuronium bromide Mylan works. For example:
- – low calcium levels in the blood (hypocalcaemia)
- – low potassium levels in the blood (hypokalaemia)
- – high magnesium levels in the blood (hypermagnesaemia), for example, when treating pre-eclampsia with magnesium salts
- – low protein levels in the blood (hypoproteinaemia)
- – lack of fluids (dehydration)
- – excess acid in the blood (acidosis)
- – excess carbon dioxide in the blood (hypercapnia)
- – general poor condition
- overweight
- burns

If any of these conditions apply to you, your doctor will take this into account when determining the correct dose of Rocuronium bromide Mylan for you.

Children and adolescents
Rocuronium bromide Mylan can be administered to children and adolescents only for the indication, as an adjunct to general anaesthesia to facilitate tracheal intubation during routine sequence induction and to provide skeletal muscle relaxation during surgery.

Other medicines and Rocuronium bromide Mylan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This will help your doctor to determine the correct dose of Rocuronium bromide Mylan for you.
The following medicines can influence the effects of Rocuronium bromide Mylan:
- Medicines that enhance the effect of Rocuronium bromide Mylan:

- some anaesthetics
- – prolonged use of corticosteroids (anti-inflammatory agents) together with Rocuronium bromide Mylan in intensive care
- – some medicines used in the treatment of bacterial infections (antibiotics**)**
– a medicine used in the treatment of bipolar disorder (lithium)
– some medicines used in the treatment of heart disease or hypertension (quinidine, calcium antagonists, beta blockers)
– a medicine used in the treatment of malaria (quinine)
– diuretics
– magnesium salts
– local anaesthetics (lidocaine and bupivacaine)
– short-term use of anticonvulsants (phenytoin), for example, during surgery.

• Medicines that reduce the effect of Rocuronium bromide Mylan:
– prolonged use of corticosteroids (anti-inflammatory agents) or anticonvulsants (phenytoin and carbamazepine)
– medicines used in the treatment of pancreatitis, abnormal coagulation and acute posthaemorrhagic anaemia (protease inhibitors; gabexate, ulinastatin).

• Medicines with a varying effect on Rocuronium bromide Mylan:
– other muscle relaxants.

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

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 pharmacist for advice before using this medicine.

Pregnancy
There are no data from the use of rocuronium bromide in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precaution, it is preferable to avoid the used of rocuronium bromide during pregnancy.
Caesarean section
A doctor will decide whether rocuronium bromide can be used in a caesarean section. It has been shown that a dose of 0.6 mg rocuronium bromide per kilogram of body weight can be safely used in a caesarean section and does not have any harmful effect on the baby.

Breast-feeding
Breast-feeding should be postponed for 6 hours after the use of this medicine.

Driving and using machines
Your doctor will tell you when you may drive a car again or use potentially dangerous machines after using Rocuronium bromide Mylan.

Rocuronium bromide Mylan contains sodium
This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially ‘sodium free’.

3. How to use Rocuronium bromide Mylan

Dose
The doctor will determine the dose of Rocuronium bromide Mylan, based on:
- what type of anaesthetic is used
- the anticipated duration of the surgery
- other medicines you are using
- your age and state of health.

You will be administered Rocuronium bromide Mylan before and/or during surgery. The normal dose is 0.6 mg rocuronium bromide per kilogram of body weight and the effect lasts 30 to 40 minutes. During surgery, the doctor will verify whether Rocuronium bromide Mylan is still working. You will be administered additional doses if necessary.

How Rocuronium bromide Mylan is administered
Rocuronium bromide Mylan is not intended for self-administration. Rocuronium bromide Mylan is injected intravenously as a solution. It is administered as a single injection or via a drip.

The injections should be administered by a doctor or a nurse.

If you are given more Rocuronium bromide Mylan than you should
As medical staff monitor your condition closely during the operation, it is unlikely that you will receive too much Rocuronium bromide Mylan. However, should this happen, artificial ventilation will be continued until you are able to breathe again. It is possible to counter the effects of Rocuronium bromide Mylan or too much Rocuronium bromide Mylan and to accelerate your recovery by giving you medicine that counteracts the effects of Rocuronium bromide Mylan.

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 noticed and treated by your doctor.
The following side effects may occur:

Common (occurs in less than 1 in 10 patients)
- Increase in heart rate (tachycardia) in children (newborn babies to adolescents)

Uncommon (occurs in less than 1 in 100 to 1,000 patients)
- increased heart rate (tachycardia) in adults
- Reduced blood pressure (hypotension)
- no or reduced or enhanced effect of Rocuronium bromide Mylan
- Pain at the injection site
- redness or itching at the injection site
- Prolongation of muscle relaxant effect of Rocuronium bromide Mylan
- delayed recovery from anaesthesia.

Very rare (occurs in less than 1 in 10,000 patients):
- allergic reactions, such as respiratory problems, changes in blood pressure or heart rate, shock (significant drop in blood pressure) due to insufficient circulating blood, or changes of the skin (for example, fluid retention, redness or rash)
- tightness of the chest caused by constriction of the respiratory muscles (bronchospasm)
- Muscle weakness or paralysis
- prolonged muscle disorder commonly seen after the use of Rocuronium bromide Mylan in combination with corticosteroids (anti-inflammatory agents) in intensive care in severely ill patients (steroid myopathy)
- problems of the respiratory tract caused by anaesthesia
- sudden fluid retention in the skin and mucous membranes (for example, throat or tongue), respiratory distress and/or itching and rashes, often as an allergic reaction (angioneurotic oedema)
- fluid retention (oedema) in the face
- skin rash, sometimes with severe itching and the formation of welts (hives or urticaria)
- redness of the skin
- excessive blushing (flushing).

Not known (frequency cannot be estimated from the available data)
- Breathing (respiratory) failure
- Stop breathing (apnoea)
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rocuronium Bromide Mylan

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, after 'EXP.'. The expiry date refers to the last day of that month.

Before opening: Store in a refrigerator (2–8°C).

Storage out of the refrigerator:
This medicine may also be stored outside of the refrigerator at a temperature of up to 30°C for a maximum 12 weeks, after which it should be discarded. 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 dilution: 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/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.

For single use only.

Do not use Rocuronium bromide Mylan if you notice any particles or visible signs of deterioration.

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 Rocuronium bromide Mylan contains

- The active ingredient is rocuronium bromide.
  Each ml of solution for injection/infusion contains 10 mg of rocuronium bromide.
  Each 5 ml vial contains 50 mg rocuronium bromide.
- The other ingredients are sodium acetate trihydrate, acetic acid (glacial), sodium chloride, sodium hydroxide and water for injections.

What Rocuronium bromide Mylan looks like and contents of the pack

Rocuronium bromide Mylan is a clear colorless to yellow or orange solution. The solution is supplied in tubular glass vials with a rubber closure and yellow flip off aluminium seal.

Rocuronium bromide Mylan is available in packs of 10 vials containing 5 ml solution.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last approved in MM/YYYY.

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The following information is intended for medicinal or healthcare professionals only:

PREPARATION GUIDE FOR USE WITH

Rocuronium bromide Mylan 10 mg/ml Solution for injection/infusion

Rocuronium bromide Mylan is administered intravenously (i.v.) either as a bolus injection or as a continuous infusion. Administration should be begun immediately after mixing, and should be completed within 24 hours.

Rocuronium bromide Mylan should be administered only by experienced staff familiar with the use of neuromuscular blocking agents. Adequate facilities and staff for endotracheal intubation and artificial ventilation have to be available for immediate use.

Incompatibilities

Physical incompatibility has been documented for Rocuronium bromide Mylan when added to solutions containing the following active substance:
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.

This medicinal product must not be mixed with other medicinal products except those mentioned in the following sections.

Mixture with other products:

Rocuronium bromide Mylan has been shown to be compatible with: sodium chloride 9 mg/ml (0.9%), glucose 50 mg/ml (5%), glucose 50 mg/ml (5%) in sodium chloride 9 mg/ml (0.9%), water for injections, Lactated Ringers solution and Haemaccel for in-use concentrations of 0.5 mg/ml and 2 mg/ml.

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

Shelf-life

Unopened vial: 2 years

After dilution: 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/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.

Storage information

Before opening: Store in a refrigerator (2–8°C)
Storage out of the refrigerator:
Rocuronium bromide solution for injection may also be stored outside of the refrigerator at a temperature of up to 30°C for a maximum 12 weeks, after which it should be discarded. 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.

Special precautions for handling

For Intravenous use only as a bolus injection or as a continuous infusion.

Administration should be begun immediately after mixing, and should be completed within 24 hours.
This medicinal product is for single use only, any unused solutions should be discarded.
The solution is to be visually inspected prior to use. Only clear solutions free from particles should be used.

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