PACKAGE LEAFLET: INFORMATION FOR THE USER

Rocuronium 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 possibile side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Rocuronium is and what it is used for

Rocuronium belongs to a group of medicines called muscle relaxants.
Normally the nerves send messages to the muscles by impulses. Rocuronium 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 may also be used if you are having an anaesthesia to ease the insertion of a tube into your trachea (windpipe) for artificial ventilation (mechanical assistance of breathing).

Rocuronium is indicated in adults and in neonates (0-27 days) infants and toddlers aged 28 days to 23 months, children aged 2 to 11 years and adolescents aged 12 to 17 years.

Rocuronium may also be used in adults only as an adjunct in the intensive care unit (ICU) (e.g. to ease the insertion of a tube into your windpipe) for short term use.

2. What you need to know before you use Rocuronium

Do not use Rocuronium
- if you are **allergic** to rocuronium bromide, the bromide ion 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 if any of the following conditions apply to you or have applied to you in the past:
- if you are **allergic** to any muscle relaxant
- if you have a **kidney,** a **liver or a gall bladder 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 have a history of **malignant hyperthermia** (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles)
- 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
Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines, such as:

- **antibiotics**
- **anti-depressants:** medicines used to treat depression (e.g. lithium salts, 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. phenytoine, carbamazepine)
- corticosteriods
- medicines used for the treatment of **myastenia gravis** (neostigmine, pyridostigmin)
- **vitamin B_1** (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:** gabexate, ulinastatin)

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) and 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 using this medicine.

For rocuronium bromide, no clinical data on exposed pregnancies and brest-feeding women are available. Rocuronium should only be given to pregnant and nursing women when the doctor decides that the benefits outweigh the risks. Rocuronium may be given during Caesarian section.
Breastfeeding should be suspended 6 hours after use of this medicine.

Driving and using machines
Rocuronium has a major influence on driving and using machines.
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.

Contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per vial (2.5 ml, 5 ml, 10ml), that is to say essentially ‘sodium- free‘.

3. How to use Rocuronium

Rocuronium will be given to you by your anaesthetist. It 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 continiously.
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.
For paediatric and elderly patients the use of Rocuronium is not recommended as an adjunct in the intensive care unit.

Use in children and adolescents
For neonates (0-27 days), infants and toddlers (28 days–23 months), children (2-11 years) and adolescents (12–17 years) the recommended doses are similar to those in adults, with the exception of continuous infusion rates in children (2-11 years) which might be higher than in adults. The anaesthetist will adapt the infusion rate accordingly.
The experience with rocuronium bromide in a special type of anaesthetic technique called rapid sequence induction is limited in paediatric patients. Rocuronium bromide is therefore not recommended for this purpose in paediatric patients.

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

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

For information intended for medicinal or healthcare professionals please see accordant section below.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypersensitivity reactions (anaphylactic reaction/shock) are very rare but may be life-threatening allergic reactions. 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 (may affect up to 1 in 100 people) / **Rare** (may affect up to 1 in 1,000 people)**:**
- Pain at the injection site
- The drug is too effective, or not effective enough, or ineffective
- The drug works longer than expected (prolonged neuromuscular block)
- The drug prolongs the narcosis (delayed recovery from anesthesia)
- Lowering of blood pressure (hypotension)
- Increase in heart rate (tachycardia)

Very rare (may affect up to 1 in 10,000 people)**:**
- Increased level of histamine (mediator of allergic reactions) in the blood
- Wheezing (bronchospasm)
- Rash, itching
- Flushing
- Swelling of the face (facial oedema)
- Wide spread, severe rash (exanthema, erythematous rash)
- Muscle weakness (myopathy)
- Welts (angioedema)
- Hives (urticaria)
- Loss of movement (flaccid paralysis)
- Failure of circulation (circulatory collaps and shock)
- Difficulty in breathing (respiratory failure, apnoea)
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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)

Paediatric patients:
In clinical studies with rocuronium bromide in paediatric patients the side effect increase in heart rate was seen in up to 1 in 10 people.

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.

For UK - You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

For Ireland: HPRA PharmacovigilanceWebsite: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rocuronium

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 and carton after “EXP.” The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Storage out of the refrigerator:

Rocuronium may also be stored outside of the refrigerator at a temperature of up to 30°C for a maximum of 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.

The product should be used immediately after opening the vial.

After dilution: Chemical and physical in-use stability of a 5 mg/ml and 0.1 mg/ml solution (diluted with sodium chloride 9 mg/ml (0.9%) and glucose 50 mg/ml (5%) solution for infusion) has been demonstrated for 24 hours at room temperature exposed to room light in glass, PE and PVC.
From the microbiological point of view, the 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 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice the solution is not clear or free from particles.

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 contains
The **active substance** is rocuronium bromide.
Each ml contains 10 mg of rocuronium bromide.

Each vial with 2.5 ml contains 25 mg rocuronium bromide.
Each vial with 5 ml contains 50 mg rocuronium bromide.
Each vial with 10 ml contains 100 mg rocuronium bromide.

The **other ingredients** are sodium acetate trihydrate, sodium chloride, glacial acetic acid 100% and water for injections.

What Rocuronium looks like and contents of the pack
Rocuronium is a clear, colourless to pale brownish-yellow solution for injection / infusion.

Pack size:
Rocuronium is available in packs of 5 or 10 vials containing 2.5 ml, 5 ml or 10 ml solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
For UK:
Fresenius Kabi Ltd
Cestrian Court
Eastgate Way, Manor Park

Runcorn, Cheshire, WA7 1NT
United Kingdom

For IE:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer:
Fresenius Kabi Austria GmbH
Hafnerstraße 36
8055 Graz
Austria

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

Austria	Rocuroniumbromid Kabi 10 mg/ml Injektionslösung/Infusionslösung
Belgium	Rocuronium bromide Fresenius Kabi 10 mg/ml oplossing voor injectie/infusie / solution injectable/solution pour perfusion / Injektionslösung/Infusionslösung
Bulgaria	Рокурониум Каби 10 mg/ml инжекционен/инфузионен разтвор
Croatia	Rokuronijev bromid Fresenius Kabi 10 mg/ml otopina za injekciju/infuziju
Czech Republic	Rocuronium Fresenius Kabi
Estonia	Rocuronium bromide Fresenius Kabi
Germany	Rocuroniumbromid Kabi 10 mg/ml Injektionslösung / Infusionslösung
Denmark	Rocuronium Fresenius Kabi
Finland	Rocuronium Fresenius Kabi 10 mg/ml injektio-/infuusioneste, liuos
France	ROCURONIUM KABI 10 mg/mL, solution injectable/pour perfusion
Hungary	Rocuronium Fresenius Kabi 10 mg/ml oldatos injekció vagy infúzió
Ireland	Rocuronium 10 mg/ml solution for injection/infusion
Italy	Rocuronio Kabi
Netherlands	Rocuroniumbromide Fresenius Kabi 10 mg/ml oplossing voor injectie/infusie
Norway	Rokuroniumbromid Fresenius Kabi
Poland	Rocuronium Kabi
Portugal	Brometo de Rocurónio Kabi
Romania	Rocuronium Kabi 10 mg/ml, soluţie injectabilă/perfuzabilă
Slovakia	Rocuronium Fresenius Kabi 10 mg/ml
Slovenia	Rokuronijev bromid Kabi 10 mg/ml raztopina za injiciranje/infundiranje
Spain	Rocuronio Kabi 10 mg/ml solución inyectable y para perfusión
Sweden	Rocuronium Fresenius Kabi injektions-/infusionsvätska, lösning
United Kingdom	Rocuronium 10 mg/ml solution for injection/infusion

This leaflet was last revised in November2020.

The following information is intended for healthcare professionals only:

For single use only.
Any unused solutions should be discarded.
The product should be used immediately after opening the vial.

Rocuronium has shown to be compatible with: sodium chloride 9 mg/ml (0,9%) and glucose 50 mg/ml (5%) solution.

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

This medicinal product must not be mixed with other medicinal products except those mentioned above.

Physical incompatibility has been documented for Rocuronium 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.