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
2. What you need to know before Rocuronium bromide is given
3. How Rocuronium bromide is given
4. Possible side effects
5. How Rocuronium bromide is stored
6. Contents of the pack and other information

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

Rocuronium bromide belongs to a group of medicines called muscle relaxants.
Muscle relaxants are used during an operation as part of a general anaesthetic. When you have an operation, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.
Rocuronium bromide may be used if you are receiving anaesthesia to ease the insertion of a tube into your trachea (windpipe) for artificial ventilation (mechanical assistance of breathing).
Rocuronium bromide can also be used in Intensive Care Units 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 to rocuronium 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, vascular, liver, gall bladder or bile duct disease
- if you have had diseases affecting nerves and muscles
- 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).

Tell your anaesthetist if any of these applies to you.

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
- loss of too much water from the body, for example by being sick, diarrhoea or sweating

- over-breathing leading to too little carbon dioxide in the blood (alkalosis)
- general ill-health
- burns
- being very overweight (obesity)
- 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 adolescence) and elderly but your anaesthetist should first assess your medical history.

Other medicines and Rocuronium bromide
Tell your anaesthetist or doctor 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.

Medicines which increase the effect of Rocuronium bromide:
- certain antibiotics
- certain medicines for heart disease or high blood pressure (water tablets, calcium channel blockers, beta-blockers and quinidine)
- certain anti-inflammatory medicines (corticosteroids)
- medicines for manic depressive illness (bipolar disorder)
- magnesium salts
- certain medicines used to treat malaria.

Medicines which decrease the effect of Rocuronium bromide:
- certain medicines for epilepsy
- calcium chloride and potassium chloride
- certain protease inhibitors called gabexate and ulinastatin.

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 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 anaesthetist for advice before being given this medicine.

<u>Pregnancy</u>
In animal studies, no adverse effects have been seen. However, there are no data from clinical studies with rocuronium bromide in pregnant women. Therefore, rocuronium bromide should be used with caution in pregnant women.

<u>Caesarean section</u>
A doctor will decide whether rocuronium bromide can be used during Caesarean section. It has been shown that the dose of 0.6 mg/kg body weight rocuronium bromide can safely be used during Caesarean section and has no harmful effect on the baby.

<u>Breast-feeding</u>
Breast-feeding 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 medicinal product contains less than 1 mmol sodium (23 mg) per 1 ml, 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).

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.

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

Very rare side effects (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 redness of the skin.

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 its size with light or other stimuli.

If any of the side effects gets 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 (NI): Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

IE: 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.
Store in a refrigerator (2°C - 8°C). Do not freeze.

Storage out of the refrigerator:
Rocuronium bromide may also be stored outside of the refrigerator at a temperature of up to 25°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.

Diluted product:
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 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 any visible signs of deterioration (e.g. particles).

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.

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 contains
- The active substance is rocuronium bromide.

1 ml of solution contains 10 mg of rocuronium bromide.
Each vial with 5 ml of solution contains 50 mg of rocuronium bromide.

- The other ingredients are sodium chloride; sodium acetate trihydrate; acetic acid, glacial (for pH adjustment); water for injections.

What Rocuronium bromide looks like and contents of the pack
Clear colourless or yellowish solution for injection/infusion.

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

Marketing Authorisation Holder and Manufacturer

AS KALCEKS
Krustpils iela 71E, Rīga, LV-1057, Latvia
Tel.: +371 67083320
E-mail: kalceks@kalceks.lv

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Estonia, Czech Republic, Norway	Rocuronium bromide Kalceks
Austria	Rocuronium Kalceks 10 mg/ml Injektions-/Infusionslösung
Croatia	Rokuronijev bromid Kalceks 10 mg/ml otopina za injekciju/infuziju
France	ROCURONIUM KALCEKS 10 mg/mL, solution injectable/pour perfusion
Hungary	Rocuronium Kalceks 10 mg/ml oldatos injekció vagy infúzió
Ireland	Rocuronium bromide 10 mg/ml solution for injection/infusion
Latvia	Rocuronium bromide Kalceks 10 mg/ml šķīdums injekcijām/infūzijām
Lithuania	Rocuronium bromide Kalceks 10 mg/ml injekcinis ar infuzinis tirpalas
The Netherlands	Rocuronium Kalceks 10 mg/ml oplossing voor injectie/infusie
Poland	Rocuronium Kalceks
Slovakia	Rocuronium bromide Kalceks 10 mg/ml injekčný/infúzny roztok
Slovenia	Rokuronijev bromid Kalceks 10 mg/ml raztopina za injiciranje/infundiranje
Spain	Rocuronio Kalceks 10 mg/ml solución inyectable y para perfusión EFG
United Kingdom (Northern Ireland)	Rocuronium bromide 10 mg/ml solution for injection/infusion

This leaflet was last revised in 06/2023

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

Rocuronium bromide 10 mg/ml solution for injection/infusion

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

Incompatibilities

Physical incompatibility has been documented for Rocuronium bromide 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 listed in SmPC Section 6.6 Special precautions for disposal and other handling.

Mixture with other products

In nominal concentrations of 0.5 mg/ml and 2.0 mg/ml Rocuronium bromide has been shown to be compatible with: 0.9% sodium chloride, 5% dextrose, 5% dextrose in saline, water for injections and Ringer lactate solution.

If Rocuronium bromide 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% sodium chloride) 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.

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 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°C - 8°C). Do not freeze.

Storage out of the refrigerator:
Rocuronium bromide may also be stored outside of the refrigerator at a temperature of up to 25°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.

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