PACKAGE LEAFLET: INFORMATION FOR THE USER

hameln

Rocuronium 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, please ask your doctor, pharmacist or nurse.
- If you get any side effects , talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 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 may also be used 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.

Children and adolescent (0 to <18 years)

Rocuronium 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 are given Rocuronium

You should NOT be given Rocuronium if you:

are **sensitive** or **allergic** to rocuronium bromide, the bromide ion or any of the other ingredients of this medicine (see section 6 for information on the other ingredients).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Rocuronium if you:
- are **allergic** to any muscle relaxant
- have a **kidney**, a **liver** or a **gallbladder disease**
- have a **heart disease** or a disease affecting your **blood circulation**
- have **an accumulation of fluid beneath the skin** (e.g. swelling of the ankles)
- have a **disease affecting the nerves and muscles** (e.g. polio (poliomyelitis), myasthenia gravis, Eaton-Lambert syndrome)
- ever developed a **drop in body temperature** (hypothermia) during anaesthesia
- have **fever** or have ever developed a **severe fever during an anaesthesia**
- have a **low calcium level** in the blood, (caused by massive transfusions)
- have a **low potassium level** in the blood, (caused for example by severe vomiting, diarrhoea or therapy to increase urination)
- have a **high magnesium level** in the blood
- have a **low level of proteins** in the blood (hypoproteinaemia)
- are **dehydrated**
- have an **increased blood acid level** (acidosis)
- have an **increased** level of **carbon dioxide** in the blood (hypercapnia)
- tend to **overbreathe** (hyperventilation). Overbreathing leads to too little carbon dioxide in the blood.
- have recently **lost a large amount of weight**
- are **overweight** or **elderly**
- have **burned your skin**

Children and the elderly

Rocuronium can be used in children (newborns and adolescents) and in the elderly but your anaesthetist should first assess your medical history. The same warnings and precautions as for adults should be taken into consideration.

Other medicines and Rocuronium

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:
- **antibiotics**
- certain medicines used to treat **depression** known as **MAOI**s (e.g. moclobemide, phenelzine, tranylcypromine)
- medicines used for the treatment of **heart disease** or **high blood pressure** (e.g. quinidine, calcium channel blocking agents, 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** (e.g. phenytoin, carbamazepine)
- corticosteroids
- medicines used for the treatment of **myasthenia gravis** (neostigmine, pyridostigmine)
- **vitamin B_1** (thiamine)
- **azathioprine** (used after transplants and for treating of auto-immune diseases)
- **theophylline** (used for the treatment of asthma)
- **noradrenaline** (a hormone which affects blood pressure and other body functions)
- **potassium chloride**
- **calcium chloride**
- medicines used for the treatment or prevention of a virus infection

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, inhaled anaesthetics), other muscle relaxants and protamines which reverse the effect of heparin (a medicine used to keep blood flowing smoothly in your blood vessels). Your doctor will take this into account when he is deciding the correct dose of rocuronium 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 pharmacist for advice before using this medicine.

There are very limited data on the use of Rocuronium during human pregnancy and no data on breast-feeding women. 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 for 6 hours after use of this medicine.

There are no data 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 following treatment.

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 contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How Rocuronium is given

Your anaesthetist will give you the injection. It is given to you into a vein either as a single injection or as a continuous infusion (over a longer period of time).

The usual dose is 0.6 mg per kg body weight and its effect will last 30 to 40 minutes.

The dose that will be given to you is determined and controlled by the anaesthetist taking into consideration the estimated length of surgery as well as your age and clinical condition.

Use in children and adolescents (0 - <18 years of age)

This medicine may be given to neonates (0 – 28 days), infants (28 days to ≤ 3 moths) and toddlers (> 3 months to ≤ 2 years), children (2-11 years) and adolescents (12 to ≤17 years). The dose and its effect in children can be slightly different from those in adults. So the anaesthetist will adjust the dose according to the needs of your child. Your doctor will take into account that for children higher infusion rates might be necessary.

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.

The following information is intended for healthcare professionals only:

PREPARATION GUIDE FOR:

hameln

Rocuronium 10 mg/ml solution for injection / infusion

It is important that you read the entire contents of this guide prior to the preparation of this medicinal product.

PREPARATION FOR INTRAVENOUS ADMINISTRATION

Rocuronium is administered intravenously (i.v.) either as a bolus injection or as a continuous infusion.

Rocuronium has been shown to be compatible with: sodium chloride 9 mg/ml (0.9%) and glucose 50 mg/ml (5%) solution.

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.

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

If you receive more Rocuronium than you should

Your anaesthetist will carefully monitor your condition during the procedure, therefore it is unlikely that you will be given too much Rocuronium. Should you be given too much your anaesthetist will make sure that anaesthesia and artificial ventilation will be continued until you breathe on your own. If you are concerned that you have been given too much, you should speak with your doctor.

Further questions

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

For information intended for medical or healthcare professionals please see the section below.

4. Possible side effects

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

Allergic reactions are rare (affects 1 to 10 users in 10,000) but may be life-threatening. An allergic 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 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 (delayed recovery from anaesthesia)
- prolonged effect of muscle relaxation (prolonged neuromuscular block)
- 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 (bronchospasm)
- airway complication of anaesthesia
- muscle weakness
- steroid myopathy
- itching, swelling, a rash or redness of the skin
- wide spread, severe rash (exanthema)
- welts (angioedema)
- hives (urticaria)
- loss of movement (paralysis)
- failure of circulation (circulatory collapse and shock)

Not known (frequency cannot be estimated from the available data):

- Breathing difficulties and breathing stops
- Severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction)
- Enlarged pupils or your pupils do not get bigger or smaller with light or other stimuli.

Children

An increase in heart rate (tachycardia) has been observed in clinical studies with a frequency of 1.4% (common) which means that it may affect up to 1 in 10 people.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 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.

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.

1 ml contains 10 mg of rocuronium bromide.

Each 2.5 ml vial contains a total content of 25 mg rocuronium bromide.

Each 5 ml ampoule/vial contains a total content of 50 mg rocuronium bromide.

Each 10 ml vial contains a total content of 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.

Pack size:

Rocuronium is available in packs of 5 or 10 vials containing 2.5 ml, 5 ml or 10 ml solution as well as in packs of 12 vials containing 5 ml or 10 ml solution. It is also available in packs of 5, 10 or 12 ampoules containing 5 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

hameln pharma ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG
United Kingdom

Manufacturer:

Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln, Germany

HBM Pharma s.r.o
Sklabinská 30
03680 Martin, Slovak Republic

hameln rds s.r.o.
Horná 36
900 01 Modra, Slovak Republic

Solupharm Pharmazeutische Erzeugnisse GmbH
Industriestraße 3
34212 Melsungen
Germany

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

AT	Rocuroniumbromid hameln 10 mg/ml Injektions-/ Infusionslösung
CZ	Rocuronium bromide hameln
DE	Rocuroniumbromid hameln 10 mg/ml Injektions-/ Infusionslösung
DK	Rocuronium ”hameln”
FI	Rocuronium hameln 10 mg/ml injektio-/ infuusioneste, liuos
HR	Rokuronijev bromid hameln 10 mg/ml otopina za injekciju/infuziju
HU	Rocuronium bromide hameln 10 mg/ml oldatos injekció/infúzió
NL	Rocuroniumbromide hameln 10 mg/ml oplossing voor injectie / infusie
PL	Rocuronium bromide hameln
SE	Rocuronium hameln 10 mg/ml injektions-/ infusionsvätska, lösning
SI	Rokuronijev bromid hameln 10 mg/ml raztopina za injiciranje/infundiranje
SK	Rocuronium bromide hameln 10 mg/ml injekčný/ infúzny roztok
UK (NI)	Rocuronium 10 mg/ml solution for injection/infusion

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HANDLING AND STORAGE

Keep out of the reach and sight of children.

The product should be used immediately after opening the vial.

Any unused solutions should be discarded.

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

Do not use Rocuronium 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)

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. 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.