

Rocuronium 10 mg/ml solution for injection / infusion

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Rocuronium Bromide

In this leaflet:

1. What Rocuronium is and what it is used for
2. Before you are given Rocuronium
3. How Rocuronium is given
4. Possible side effects
5. How to store Rocuronium
6. Further information

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 receiving anaesthesia to ease the insertion of a tube into your trachea (windpipe) for artificial ventilation (mechanical assistance of breathing).

2. 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 Rocuronium (see section 6 for information on the other ingredients).

Take special care with Rocuronium

Before you are given Rocuronium, tell your doctor 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**

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, such as:

- **antibiotics**
- certain medicines used to treat **depression** known as **MAOIs** (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 B₁** (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 and breast-feeding

Ask your doctor or pharmacist for advice before using any 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.

Driving and using machines

Rocuronium has a major influence on driving and using machines.

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

PREPARATION GUIDE FOR:

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)

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.

Important information about some of the ingredients of Rocuronium

This medicinal product 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.

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 product, please ask your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rocuronium 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.

Very common (affects more than 1 user in 10):

- Pain at the injection site

Very rare (affects less than 1 user in 10,000):

- Breathing difficulties, reddened skin, sickness, headache and diarrhoea (due to increased histamine levels in the blood)
- Failure of circulation (circulatory collapse and shock)
- Lowering of blood pressure (the symptoms are dizziness, tiredness, cold hands and feet)
- Increase in heart rate
- Wheezing
- Itching or rash
- Widespread, severe rash
- Welts
- Hives
- Prolonged muscle relaxation
- Loss of movement

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

- Breathing difficulties and breathing stops
- Muscle weakness

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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.

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

5. HOW TO STORE ROCURONIUM

Keep out of the reach and sight of children.

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).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 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.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

hameln pharma plus gmbh
Langes Feld 13
31789 Hameln
Germany

Manufacturer:

hameln pharmaceuticals gmbh
Langes Feld 13
31789 Hameln
Germany

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

DE	Rocuroniumbromid-hameln 10 mg/ml Injektionslösung / Infusionslösung
DK	Rocuronium Hameln 10 mg/ml Injektions- og infusionsvæske, opløsning
FI	Rocuronium Hameln 10 mg/ml injektio-/infusioneste, liuos
NL	Rocuronium bromide-hameln 10 mg/ml oplossing voor injectie
SE	Rocuronium Hameln 10 mg/ml injektions-/infusionsvätska, lösning
UK	Rocuronium 10 mg/ml solution for injection/infusion

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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 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.