What is in this leaflet

Information for you.

Read all of this leaflet carefully before you are given this medicine. Because it contains important information about:

- 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 this leaflet

1. What Rocuronium bromide is and what it is used for
2. What you need to know before you receive Rocuronium bromide
3. How much of Rocuronium bromide is given
4. How Rocuronium bromide is used
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. Rocuronium bromide is given as part of the induction to 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 of your lungs. It may be used to give anaesthetic agents to produce the correct dose of Rocuronium bromide for you. 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 medicines and Rocuronium bromide

Tell your anaesthetist if any of these applies to you.

- if you have a history of malignant hyperthermia
- you are allergic to rocuronium or any of the other medicines called muscle relaxants
- you have had diseases affecting nerves and muscle (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles)
- you have fluid retention (oedema)
- you have fluid retention (oedema)
- if you are allergic to muscle relaxants
- you have recently taken or might take any other medicines. This includes medicinal 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
- certain medicines called muscle relaxants

Medicines which decrease the effect of Rocuronium bromide:

- certain medicines for epilepsy
- high magnesium levels in the blood
- certain medicines for manic depressive illness (bipolar disorder)
- calcium chloride and potassium chloride
- medicines for manic depressive illness (bipolar disorder)

2. What you need to know before you receive Rocuronium bromide

You should not receive Rocuronium bromide:

- if you are allergic to Rocuronium bromide or any of the other ingredients of this medicine (listed in section 6).
- if you have myasthenia gravis
- if you have had kidney, liver, 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 had jaundice
- if you have had diseases affecting nerves and muscles
- when deciding the correct dose of Rocuronium bromide. These include certain medicines for epilepsy, 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.

Rocuronium bromide will take this into account when deciding the correct dose of Rocuronium bromide for you.

3. How much of Rocuronium bromide is given

You should not receive Rocuronium bromide:

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

Talk to your anaesthetist if this applies to you.

Warnings and precautions

Tell 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

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 magnesium levels in the blood
- high potassium levels in the blood
- high calcium levels in the blood
- low carbon dioxide in the blood
- low levels of protein in the blood
- very low body temperature (hypothermia)
- very low oxygen levels in the body (hypoxia)
- very low body temperature (hypothermia)
- severe sepsis
- severe burns
- being overweight (obesity)
- being very overweight (obesity)
- low levels of magnesium in the blood
- low levels of magnesium in the blood
- low levels of potassium in the blood
- low levels of potassium in the blood
- too much carbon dioxide in the blood
- low levels of protein in the blood
- loss of too much water from the body, for example by being sick, diarrhoea or sweating
- loss of too much water from the body, for example by being sick, diarrhoea or sweating
- other medicines. This includes medicinal 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
- certain medicines called muscle relaxants

Medicines which decrease the effect of Rocuronium bromide:

- certain medicines for epilepsy
- high magnesium levels in the blood
- certain medicines for manic depressive illness (bipolar disorder)
- calcium chloride and potassium chloride
- medicines for manic depressive illness (bipolar disorder)

4. How Rocuronium bromide is used

Rocuronium bromide may cause certain anaesthetics to 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.

Pregnancy

Studies in animals, 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.

Caesarean section

A doctor will decide whether rocuronium bromide can be used during Caesarean section. It has been used in pregnancy, the use of 0.6 mg/kg for the latest dose of rocuronium bromide can safely be used during Caesarean section and has no harmful effect on the baby.

Breast-feeding

Rocuronium bromide 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, disoriented and confused for a few hours after the anaesthetic. You may be given another medicine which will help you be more alert. Because Rocuronium bromide may make certain anaesthetics work more quickly, 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 (23 mg) per 1 ml, that is to say essentially "sodium-free".

5. 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

Calcium chloride and potassium chloride

Some conditions may influence the effects of Rocuronium bromide - for example:

- low calcium levels in the blood
- low magnesium levels in the blood
- high potassium levels in the blood
- high calcium levels in the blood
- low carbon dioxide in the blood
- low levels of protein in the blood
- very low body temperature (hypothermia)
- very low oxygen levels in the body (hypoxia)
- low levels of magnesium in the blood
- low levels of magnesium in the blood
- low levels of potassium in the blood
- low levels of potassium 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
- other medicines. This includes medicinal 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
- certain medicines called muscle relaxants

Medicines which decrease the effect of Rocuronium bromide:

- certain medicines for epilepsy
- high magnesium levels in the blood
- certain medicines for manic depressive illness (bipolar disorder)
- calcium chloride and potassium chloride
- medicines for manic depressive illness (bipolar disorder)
Uncommon side effects

The normal dose is 0.6 mg per kg body weight and how this takes place. This happens, your anaesthetist will keep you breathing artificially (by a ventilator) until you can breathe on your own. You will be kept aseptic while you are in theatre.

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 size
- pain near the site of injection.

Very rare side effects (may affect up to 1 in 10,000 people)

- allergy (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 reaction (see section 4.4)
- sensitivity to rocuronium acetate trihydrate; acetic acid, sodium chloride; sodium acetate tributyrate; acetic acid, glycerol (for pH adjustment), water for injections.

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.

Thereafter:

- the infusion line is adequately mixed, and should be completed within 24 hours.
- Signs of deterioration (e.g. particles).

Any unused product or waste material should be discarded. The product should not be placed back into the refrigerator, once it has been kept outside.

The shelf-life period must not exceed the shelf-life.

The following information is intended for medical 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 substances:

- Amphotericin B (polymerised lipid complexes), ampicillin, aminoglycosides, ceftazidime, cefotaxime, ceftriaxone, chloramphenicol, cyclosporine, digitoxin, doxorubicin, ethanolamine, etilefrine, epinephrine, esmolol, furosemide, frusemide, hydralazine, hydroxyethyl starch, indomethacin, irinotecan, ketorolac, laboratories, methylprednisolone, midazolam, methylprednisolone sodium succinate, morphine, nitrofurantoin, nitroglycerin, nitroprusside, ondansetron, omeprazole, oxaliplatin, paclitaxel, pentamidine, phenylephrine, potassium chloride, propofol, ranitidine, thiopental, tocollic, troglitazone, vancomycin.

This medicinal product must not be mixed with other medicinal products except those listed in SmPC Section 4.9 Special precautions for disposal and other handling.

Mixture with other products

Rocuronium bromide 45 mg/mL (maximum 3 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) after administration of Rocuronium bromide and medicinal products for which incompatibility with Rocuronium bromide has been demonstrated or for dilution.

Diluted product

When mixed 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, there is a risk of bacterial contamination prior to use are the responsibility of the user and should 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 dispose of any medicines you no longer need. These measures will help protect the environment.

What Rocuronium bromide contains

- The active substance is rocuronium bromide.

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

The other ingredients are sodium chloride; sodium acetate tributyrate; acetic acid, glycerol (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

AS KALCEKS

Krustpils iela 53, Riga, LV-1057, Latvia

Tel: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

Yellow Card Scheme

Manufacturer

AS KALCEKS

Krustpils iela 53, Riga, LV-1057, Latvia

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

Austria

Rocuronium Kalceks 10 mg/ml injektions-Lösung

Rokuronijev bromid Kalceks 10 mg/ml injektije/supot

Croatia

Rocuronium bromide Kalceks 10 mg/ml solution injectable/spray

Estonia

Rocuronium bromide Kalceks 10 mg/mL, solution injectable/spray

France

RUCORONIUM KALCEKS 10 mg/mL, solution injectable/spray

Hungary

Rocuronium Kalceks 10 mg/ml olajos injekció/spray

Iceland

Rocuronium bromide 10 mg/ml solution for injection/infusion

Ireland

Rocuronium Kalceks 10 mg/ml solution for injection/infusion

Latvia

Rocuronium bromide Kalceks 10 mg/ml olajos injekciós spray

Lithuania

Rocuronium bromide Kalceks 10 mg/ml ungudėmams ar infiltracijoms

The Netherlands

Rocuronium Kalceks 10 mg/ml oplossing voor injectie/infiltratie

Norway

Rocuronium Kalceks 10 mg/ml injectisjonssolns

Poland

Rocuronium Kalceks 10 mg/ml dożywotnia

Slovakia

Rocuronium bromide Kalceks 10 mg/ml injekčná roztok

Slovenia

Rocuronium bromide Kalceks 10 mg/ml injekcijski roztok

United Kingdom

Rocuronium bromide Kalceks 10 mg/ml injection/infusion solution for injection/infusion

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