PACKAGE LEAFLET

Package leaflet: Information for the user

Rocuronium bromide Accord 10 mg/ml solution for injection in pre-filled syringe
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 or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

Rocuronium bromide Accord is a muscle relaxant used in adults and children from 2 years of age.

Muscle relaxants are used during a surgical procedure to assist in general anaesthesia. During a surgical procedure, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the surgical procedure. Normally, the nerves send signals to your muscles. Rocuronium bromide Accord can temporarily block these signals, thereby causing your muscles to relax. Because the muscles needed for breathing also relax, you will be given artificial respiration until you can breathe on your own again. During the surgical procedure, the effect of the muscle relaxant will be constantly monitored and if necessary, you will be given some more Rocuronium bromide Accord. At the end of surgery, the effects of Rocuronium bromide Accord are allowed to wear off and you can start breathing on your own. Sometimes, another medicine will be given to speed up this recovery. Rocuronium bromide Accord can also be used in intensive care.

2. What you need to know before you use Rocuronium bromide Accord

You must not be given Rocuronium bromide Accord
- if you are allergic to rocuronium or any of the other ingredients of this medicine (listed in section 6).

Tell your doctor if this applies to you.

Warnings and precautions
Your medical history can affect the way in which you are given Rocuronium bromide Accord. Tell your doctor if you have, or have ever had, the following:
- an allergy to muscle relaxants
- poor kidney function (renal impairment) or kidney disease
- a cardiovascular disease
- oedema formation (fluid accumulation, e.g. on your ankles)
- liver disease, gallbladder or bile duct disease or poor liver function
- diseases affecting the nerves and muscles
- history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles)

Some medical conditions may affect the way Rocuronium bromide Accord works. For example:
- low potassium levels in the blood (hypokalaemia)
- high magnesium levels in the blood (hypermagnesaemia), e.g. when treating toxaemia of pregnancy with magnesium salts
- low calcium levels in the blood (hypocalcaemia)
- low protein levels in the blood (hypoproteinaemia)
- lack of fluids (dehydration)
- too much acid in the blood (acidosis)
- too much carbon dioxide in the blood (hypercapnia)
- general weak condition
- being overweight
- burns

If any of these conditions apply to you, your doctor will take this into account when deciding on the right dose of Rocuronium bromide Accord for you.

Children and adolescents
Rocuronium bromide Accord can be used in children (2 – 11 years) and adolescents (12 – 17 years). However, maintenance dosage is not indicated in paediatric population under 12 years of age.

Rocuronium bromide Accord should not be given to children under 2 years because the subgraduations of the pre-filled syringes do not allow an accurate administration of the product in this population.

Other medicines and Rocuronium bromide Accord
Tell your doctor if you are using, have recently used or might use any other medicines. This will help your doctor determine the right dose of Rocuronium bromide Accord for you.

The following medicines may influence the effect of Rocuronium bromide Accord:

Medicines which increase the effect of Rocuronium bromide Accord:
- certain anaesthetics
- medicine used to relax muscles (suxamethonium)
- certain medicines used to treat bacterial infections (antibiotics)
- certain medicines used for manic depressive illness (lithium)
- certain medicines for heart disease or high blood pressure (quinidine, calcium channel blockers, beta-blockers)
- certain medicines used to treat malaria (quinine)
- water tablets (diuretics)
- magnesium salts
- local anaesthetics (lidocaine and bupivacaine)
- short-term use of medicines for epilepsy (phenytoin), e.g. during surgery.

Medicines which decrease the effect of Rocuronium bromide Accord:
- long-term use of corticosteroids (anti-inflammatory medicines) or medicines for epilepsy (phenytoin and carbamazepine)
- medicines for pancreatitis, problems with blood clotting and acute blood loss (protease inhibitors: gabexate, ulinastatin)
- Calcium chloride, potassium chloride.

Medicines with a variable effect on Rocuronium bromide Accord:
- other medicines used to relax the muscles.

Rocuronium bromide Accord may influence the effect of the following medicines:
- The effect of local anaesthetics (lidocaine) may be increased.

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 for advice before you are given this medicine.

There are very limited data on the use of rocuronium bromide during human pregnancy and no data on breast-feeding women. Rocuronium bromide Accord should only be given to pregnant and nursing women when the doctor decides that the benefits outweigh the risks.

This medicine may be given during Caesarian section.

Driving and using machines
Your doctor will tell you when you can resume driving or using dangerous machines after the use of Rocuronium bromide Accord.

Rocuronium bromide Accord contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially "sodium-free".

3. How to use Rocuronium bromide Accord

Dosage
Your doctor will determine the dosage of Rocuronium bromide Accord, based on:
- which type of anaesthetic is used
- the expected length of the surgical procedure
- other medicines you are using
- your age and state of health.

You will be given Rocuronium bromide Accord before and/or during a surgical procedure by a healthcare professional. The normal dose is 0.6 mg rocuronium bromide per kilo of body weight and the effect lasts 30 to 40 minutes. During the procedure, it will be checked whether Rocuronium bromide Accord is still working. You will be given additional doses, if needed.

How Rocuronium bromide Accord is given
Rocuronium bromide Accord is not intended for self-administration. Rocuronium bromide Accord will be injected as a solution into a vein. It will be given by a single injection.

If you receive more Rocuronium bromide Accord than you should
As the medical staff will be monitoring your condition carefully, it is unlikely that you will be given too much Rocuronium bromide Accord. However, if this happens, artificial respiration will be continued until you can breathe again on your own. It is possible to counter the effects of (too much) Rocuronium bromide Accord and speed up your recovery, by giving you a medicine that counteracts the effects of Rocuronium bromide Accord.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If these side effects occur during anaesthesia, they will be seen and treated by your doctor.

The following side effects may occur:

Uncommon/rare (may affect less than 1 in 100/1 000 people)
- rapid heartbeat (tachycardia)
- low blood pressure (hypotension)
- Rocuronium bromide Accord has no effect, or is too effective or not effective enough
- pain at the injection site

- redness or itching at the injection site
- prolongation of the muscle-relaxant effect of Rocuronium bromide Accord
- delayed recovery from anaesthesia

Very rare (may affect less than 1 in 10 000 people)
- allergic reactions, such as breathing difficulties, changes in blood pressure or heart rate, shock (sharp drop in blood pressure) due to insufficient circulating blood, or skin changes (e.g. fluid accumulation, redness or rash)
- excessive and prolonged contraction of the airway muscles causing breathing difficulty (bronchospasm)
- muscle weakness or paralysis
- sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue),breathing difficulties and/or itching or rash, often as an allergic reaction (angioedema)
- fluid accumulation (oedema) in the face
- airway problems due to the anaesthetic
- rash, sometimes with severe itching and whealing (hives or urticaria)
- skin redness
- flushing

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 in size with light or other stimuli.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance,
Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rocuronium bromide Accord

Keep this medicine out of the sight and reach of children.
Rocuronium bromide Accord is stored in the hospital. Store in a refrigerator (2°C to 8 °C).

Storage out of the refrigerator: Rocuronium bromide Accord 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 product cannot be used after the expiry date stated on the packaging.

The pre-filled syringe is for single patient only.

Do not use this medicine after the expiry date which is stated on the box (Twist box) and syringe label after EXP. The expiry date refers to the last day of that month.

Do not use Rocuronium bromide Accord if you notice that the solution contains particles or is not clear.

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 Accord contains
The active substance is rocuronium bromide: Each ml solution contains 10 mg rocuronium bromide.

Each 5 ml pre-filled syringe contains 50 mg rocuronium bromide.
Each 10 ml pre-filled syringe contains 100 mg rocuronium bromide.

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

What Rocuronium bromide Accord looks like and contents of the pack

Rocuronium bromide Accord is a sterile clear, colourless to pale brownish yellow solution filled in a clear glass pre-filled syringe free from foreign visible particles.

5 ml clear glass pre-filled syringe with tip cap, plunger stopper (grey bromobutyl rubber stopper) and plunger rod (polypropylene). Graduations per 0.1 ml are present on the barrel of the syringe.

10 ml clear glass pre-filled syringe with tip cap, plunger stopper (grey bromobutyl rubber stopper) and plunger rod (polypropylene). Graduations per 0.2 ml are present on the barrel of the syringe.

Pack size: one pre-filled syringe

The pre-filled syringe is supplied without needle, packaged in an outer plastic box (Twist box).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House, Euro Business Park,
Little Island, Cork, T45 K857,
Ireland

Manufacturer
Accord Healthcare Polska Sp.z o.o.
ul. Lutomierska 50,
95-200 Pabianice
Poland

Or

Laboratori Fundació Dau
Pol. Ind. Consorci Zona Franca. c/ C, 12-14
08040 BARCELONA (Barcelona), Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Austria	Rocuroniumbromid Accord 10 mg/ml Injektionslösung in einer Fertigspritze
Germany	Rocuroniumbromid Accord 10 mg/ml Injektionslösung in einer Fertigspritze
Denmark	Rocuronium bromide Accord

Finland	Rocuronium Accord 10 mg/ml injektioneste, liuos, esitäytetty ruisku
Netherlands	Rocuroniumbromide Accord 10 mg/ml oplossing voor injectie in een voorgevulde spuit
Norway	Rocuronium bromide Accord
Sweden	Rocuronium Accord 10 mg/ml injektionsvätska, lösning i förfylld spruta
Spain	Rocuronio Accord 10 mg/ml solución inyectable en jeringa precargada
Portugal	Brometo de Rocurónio Accord
Italy	Rocuronio Accord
Ireland	Rocuronium bromide Accord 10 mg/mL solution for injection in pre filled syringe
Czech Republic	Rokuronium bromid Accord

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The following information is intended for healthcare professionals only:

The pre-filled syringes are not suitable for accurate administration of the product in children younger than 2 years of age.
The user should be aware of the different subgraduations of the two available pre-filled syringes (graduations per 0.1 ml for the 5 ml syringe and graduations per 0.2 ml for the 10 ml syringe).

The pre-filled syringe is for single patient only. Discard syringe after use. Do not reuse.

Aspect of the solution
The product should be inspected visually for particles and discoloration prior to administration. Only a clear colourless to pale brownish yellow solution free from particles or precipitates should be used. Do not use this medicine if you notice visible signs of deterioration.

Incompatibilites of the solution
Rocuronium bromide is physically incompatible with solutions of the following medicinal products: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, methohexital, methylprednisolone, prednisolone sodium succinate, thiopental, trimethoprim and vancomycin. Rocuronium bromide is also incompatible with intralipid.

Use of the pre-filled syringe

The pre-filled syringe is for single patient only.

The pre-filled syringe is not suitable for syringe pump drivers. The pre-filled syringe is a ready to administer product, it is not suitable for dilution in an infusion pouch.

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