Package leaflet: Information for the user

Rocuronium B. Braun 10 mg/ml solution for injection / infusion
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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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. See section 4.

What is in this leaflet:

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

Rocuronium name belongs to a group of medicines called muscle relaxants.
Under normal circumstances your nerves send messages to the muscles by impulses. Rocuronium name 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.

In *adults and children*, if you are under general anaesthesia, rocuronium name may be used to ease the insertion of a tube into your windpipe (trachea) to help you breath (mechanical assistance of breathing) and to assure that your muscles are relaxed during surgery.
If you are an *adult* your doctor may also use this medicine for a short time as an additional medicine in the intensive care unit (ICU) (e.g. to ease the insertion of a tube into your windpipe). In addition you may also receive this medicine whenever there is an emergency situation and you need to receive a tube into your windpipe very quickly to prepare for surgery.

2. What you need to know before you use Rocuronium name

Do not use Rocuronium name
- if you are **allergic** to rocuronium, bromide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using this medicine
- if you are *allergic* to any muscle relaxant
- if you have a *kidney***,** a *liver* or a *biliary disease*
- if you have a *heart disease* or a disease affecting your *blood circulation*

- if you have one of your body areas is swelling due to water incorporation (*oedema* e.g. in the ankle area)
- if you have a *disease affecting the nerves and muscles* (neuromuscular diseases, e.g. polio (poliomyelitis), myasthenia gravis, Eaton-Lambert syndrome)
- if you ever developed a *too low body temperature during an anaesthesia* (hypothermia)
- if you have a *low calcium level* in the blood (hypocalcaemia), (caused for example by massive transfusions)
- if you have a *low potassium level* in the blood (hypokalaemia), (caused for example by severe vomiting, diarrhoea or diuretic therapy)
- if you have a *high magnesium level* in the blood (hypermagnesaemia)
- if you have a *low level of proteins* in the blood (hypoproteinaemia)
- if you suffer from *dehydration*
- if you have *an increased amount of acids* in the blood (acidosis)
- if you have *an increased amount of carbon dioxide* in the blood (hypercapnia)
- if you suffer from an *excessive loss of weight* (cachexia)
- if you are *overweight* or *elderly*
- if you have *burns*

Other medicines and Rocuronium name
Your doctor or pharmacist has to know if you are taking, have recently taken or might take any other medicines, such as:
- *antibiotics*
- *anti-depressant medicines* containing lithium
- medicines used for the treatment of *heart diseases* or *high blood pressure* (e.g. quinidine, calcium channel blocking agents, adrenergic blocking agents (e.g. beta blockers, alpha-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 treatment* (e.g. phenytoin, carbamazepine)
- long-term use of *corticosteroids* in the ICU
- medicines used for the treatment of *myasthenia gravis* (neostigmine, pyridostigmine, edrophonium, aminopyridine),
- *theophylline* (used for the treatment of asthma)
- medicines used for the treatment or prevention of a virus infection (protease inhibitors)

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, inhalational anaesthetics),, other muscle relaxants, protamine which reverses the anticoagulant effect (prevention of blood clots) of heparin. Your doctor will take this into account when he is deciding the correct dose of rocuronium for you.

Pregnancy and 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 name during human pregnancy and no data on breast-feeding women. Rocuronium name should only be given to pregnant and nursing women when the doctor decides that the benefits outweigh the risks. Rocuronium name may be given during Caesarean section.
There are no data available on the influence of this medicine on your fertility.

Driving and using machines
Rocuronium name 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 after full recovery from the effect of this medicine.

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 name contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free‘.

3. How to use Rocuronium name

Rocuronium name will be given to you by your anaesthetist. It is given to you intravenously either as a single injection or as a continuous infusion (over a longer period of time) into a vein.

Adults
The usual dose is 0.6 mg per kg body weight and its effect will last 30 to 40 minutes. During surgery the effect of Rocuronium name is controlled continously. Therefore your doctor may administer further amounts of this medicine to you depending on your individual situation.
If necessary, additional doses could be administered to you. The dose is adjusted to your needs by your anaesthetist. It depends on many factors, such as drug interactions (their cross activity), taking into consideration the estimated length of surgery as well as your age and clinical condition.
This medicinal product is for single use only.

Use in children and adolescents
This medicine may be given to neonates (0 - 27 days), infants (28 days to 2 months) and toddlers (3 months to 23 months), children (2-11 years) and adolescents (12 to≤17 years). 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 children and adolescents. Rocuronium bromide is therefore not recommended for this purpose in children and adolescents.

Older patients, obese/overweight patients and patients with liver and/or bile diseases and/or kidney failure:
Your doctor might need to adapt the dosage you will receive depending on your individual situation.

If you receive more Rocuronium name than you should
Your anaesthetist will carefully monitor you when you are under medication of Rocuronium name, therefore it is unlikely that you will be given too much Rocuronium name. If it happens, muscle relaxation might increase. Then your anaesthetist may give you medicines to reverse this effect and will make sure that anaesthesia and artificial ventilation will be continued until you breathe on your own again.

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 medicinal or healthcare professionals please see accordant section below.

4. Possible side effects

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

The following side effects may be serious. If any of the following side effects occur, inform your doctor or nurse immediately:

Very rare (may affect up to 1 in 10 000 people):
Hypersensitivity reactions (allergic reactions) and symptoms associated with it. A hypersensitivity reaction may include rash, itching, difficulty in breathing, low blood pressure, fast heart beat, circulatory collapse, shock or swelling of the face, lips, throat or tongue, hives, welt, reddening of the skin. In addition during anaesthesia there might occur the situation that you get other difficulties with your breathing system (airway complication of anaesthesia).
Not known (cannot be estimated from the available data):

- Stopping breathing
- respiratory failure
- severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction)

Other side effects include:

Uncommon/rare (may affect between to 1-10 in 1 000 people):

- Increase in heart rate (tachycardia)*
- Delayed recovery from anaesthesia
- Lowering of blood pressure (hypotension)
- Medicine was ineffective
- Effect of the medicine in general was increased or decreased
- Response of your body to this medicine may be increased or decreased
- Pain at the injection site
- Prolonged effect of muscle relaxation (prolonged neuromuscular block)

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

- Increased level of histamine in the blood
- Wheezing (bronchospasm)
- Loss of movement (flaccid paralysis)
- muscle weakness (after long-term use of this medicine in the ICU, especially if administered with cortisone)

*Clinical studies suggest that in *paediatric patients* an increase in heart rate is common and may affect up to 1 in 10 people.

Reporting of side effects
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. You can also report side effects directly via

the national reporting system listed in Appendix V.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rocuronium name

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.

Do not store above 25°C.

After first opening: The product should be used immediately after opening the ampoule.

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 exposed to room light in glass, and plastic containers. 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.

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

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 name contains
The **active substance** is rocuronium bromide.
1 ml contains 10 mg of rocuronium bromide.

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

The **other ingredients** are gluconolactone, sodium acetate trihydrate, sodium citrate dihydrate, , and water for injections.

What Rocuronium name looks like and contents of the pack
Rocuronium name is a clear, colourless to pale brownish-yellow solution for injection / injusion.

Pack size:
Rocuronium name is available in packs of 20 plastic ampoules containing 5 ml solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany
Postal address:
34209 Melsungen
Germany
Phone: +49 5661/71-0
Fax: +49 5661/71-4567

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

Austria	Rocuroniumbromid B. Braun 10 mg/ml
Belgium	Rocuronium B. Braun 10 mg/ml oplossing voor injectie/infusie
Czech Republic	Rocuronium B. Braun 10 mg/ml
Germany	Rocuroniumbromid B. Braun 10 mg/ml
Spain	Rocuronio B. Braun 10 mg/ml
Finland	Rocuronium B. Braun 10 mg/ml
Greece	Rocuronium B. Braun 10 mg/ml
Ireland	Rocuronium 10 mg/ml
Italy	Rocuronio B. Braun 10 mg/ml
Luxembourg	Rocuroniumbromid B. Braun 10 mg/ml
Netherlands	Rocuroniumbromide B. Braun 10 mg/ml
Poland	Rocuronium B. Braun
Portugal	Brometo de Rocurónio B. Braun
Sweden	Rocuronium B. Braun 10 mg/ml
Slovak Republic	Rocuronium B. Braun 10 mg/ml
United Kingdom	Rocuronium 10 mg/ml

This leaflet was last approved in.

The following information is intended for healthcare professionals only:

Preparation guide for:
Rocuronium name 10 mg/ml solution for injection

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

Preparation for the intravenous administration
For single use only.
Rocuronium name is administered intravenously (i.v.) either as a bolus injection or as a continuous infusion.
Rocuronium name has been shown to be compatible with: sodium chloride 9 mg/ml (0.9%) and glucose 50 mg/ml (5%) solution.

Any unused solutions should be discarded.

This medicinal product must not be mixed with other medicinal products except those mentioned above.

Physical incompatibility has been documented for Rocuronium name 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 name 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 name and medicinal products for which incompatibility with Rocuronium name has been demonstrated or for which compatibility with Rocuronium name has not been established.