Patient Information Leaflet for Human Medicines

SCHEDULING STATUS: S5

PATIENT INFORMATION LEAFLET

ROCURONIUM 50 mg B Braun , Intravenous solution for injection

Rocuronium bromide

Sugar free

Read all of this leaflet carefully before you are given ROCURONIUM 50 mg B Braun

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- **ROCURONIUM 50 mg B Braun** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What **ROCURONIUM 50 mg B Braun** is and what it is used for
2. What you need to know before **ROCURONIUM 50 mg B Braun** is administered to you
3. How **ROCURONIUM 50 mg B Braun** will be administered to you
4. Possible side effects
5. How to store **ROCURONIUM 50 mg B Braun**
6. Contents of the pack and other information

What ROCURONIUM 50 mg B Braun is and what it is used for

ROCURONIUM 50 mg B Braun belongs to a group of medicines called muscle relaxants.

Muscle relaxants are used during an operation as part of the general anaesthesia. When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

ROCURONIUM 50 mg B Braun can also be used in the Intensive Care Unit to keep your muscles relaxed and to help relax the muscles of your throat when you need to be put on a breathing tube, (ventilated).

What you need to know before you are given ROCURONIUM 50 mg B Braun

You should not be given ROCURONIUM 50 mg B Braun :

If you are hypersensitive (allergic) to rocuronium, the bromide ion or any of the other ingredients of **ROCURONIUM 50 mg B Braun** (listed in section 6).

If your child is under 1 month old.

ROCURONIUM 50 mg B Braun is not recommended for the facilitation of mechanical ventilation in the intensive care in children and elderly patients in the Intensive Care Unit (ICU).

The safety in pregnancy and lactation has not been demonstrated.

Warnings and precautions

Take special care with ROCURONIUM 50 mg B Braun

Tell your doctor/anaesthetist or healthcare provider before you receive **ROCURONIUM 50 mg B Braun**:

- If you are allergic to muscle relaxants.
- If you have had kidney, heart, liver or gall bladder diseases.
- If you have had diseases affecting nerves and muscles.

- If you have fluid retention (oedema).
- If you have had malignant hyperthermia (severe fever) during anaesthesia.

Some conditions may influence the effects of **ROCURONIUM 50 mg B Braun** e.g.

- If you have low calcium levels in the blood.
- If you have low potassium levels in the blood.
- If you have high magnesium levels in the blood.
- If you have low levels of protein in the blood.
- If you have too much carbon dioxide in the blood.
- If you have increased blood acid levels.
- Loss of too much water from the body e.g. by being sick, diarrhoea or sweating.
- Over-breathing leading to too little carbon dioxide in the blood (alkalosis).
- If you have general ill-health.
- If you have burns.
- If you are overweight (obesity).
- If you have ever developed a very low body temperature (hypothermia).

If you are suffering from any of these conditions your anaesthetist/doctor will take this into account when deciding on the correct dose of **ROCURONIUM 50 mg B Braun** for you.

Children

ROCURONIUM 50 mg B Braun should not be given to newborn babies up to 1 month.

Other medicines and ROCURONIUM 50 mg B Braun:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking or using any of the following medicines:

Medicines which increase the effect of ***ROCURONIUM 50 mg B Braun****:*

- Certain medicines which are used to treat bacterial infections (antibiotics).
- Certain medicines for heart disease or increased blood pressure (water tablets, calcium blockers, beta-blockers and quinidine).
- Certain anti-inflammatory medicines (corticosteroids).
- Medicines for manic depressive illness (bipolar disorder).
- Magnesium salts.
- Certain medicines used to treat malaria.
- Local anaesthetics such as lignocaine.

*Medicines which decrease the effect of **ROCURONIUM 50 mg B Braun**:*

- Certain medicines for epilepsy (e.g. phenytoin, carbamazepine).
- Calcium chloride and potassium chloride.
- Certain protease inhibitors called gabexate and ulinastatin (used to treat or prevent some virus infections).

In addition, you may be given other medicine before or during surgery which can alter the effects of **ROCURONIUM 50 mg B Braun**. These include certain anaesthetics, other muscle relaxants, suxamethonium to assist with inserting a breathing tube, medicines such as phenytoin and medicines which reverse the effects of **ROCURONIUM 50 mg B Braun**.

ROCURONIUM 50 mg B Braun may make certain anaesthetics work more quickly. Your anaesthetist will take this into account when deciding the correct dose of **ROCURONIUM 50 mg B Braun** for you.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, inform your doctor, anaesthetist or other healthcare professional for advice.

The safety is not established. You should not be given **ROCURONIUM 50 mg B Braun** if you are pregnant or breastfeeding.

You may be given **ROCURONIUM 50 mg B Braun** if you are having a caesarean section.

Driving and using machines

Your doctor will inform you when it is safe to drive and operate potentially dangerous machinery after you have been administered **ROCURONIUM 50 mg B Braun**. You may feel tired, weak or dizzy, have muscle weakness for some time after you have an operation where you are given **ROCURONIUM 50 mg B Braun.**

Do not drive or use any tools or machines if you feel tired or sleepy from the treatment with **ROCURONIUM 50 mg B Braun** until you have recovered completely from the effects of **ROCURONIUM 50 mg B Braun**.

3. How to receive ROCURONIUM 50 mg B Braun

You will not be expected to give yourself **ROCURONIUM 50 mg B Braun**. It will be given by a doctor qualified to do so.

ROCURONIUM 50 mg B Braun will be given to you by your anaesthetist. **ROCURONIUM 50 mg B Braun** is given intravenously (into the vein), either as single injections or as a continuous infusion (a drip).

Your anaesthetist will work out the dose of **ROCURONIUM B Braun 50 mg** you need based on:

- the type of anaesthetic you will be given during the operation
- the expected length of the operation
- other medicines you are taking
- your general state of health.

The normal dose is 0,6 mg per kg body weight and the effect will last 30 – 40 minutes.

You will be given **ROCURONIUM 50 mg B Braun** before and/or during a surgical procedure. During the procedure it will be checked whether **ROCURONIUM 50 mg B Braun** is still working. You may be given additional doses if they are needed.

If you are given more ROCURONIUM 50 mg B Braun than you should

Since your anaesthetist or doctor will be administering **ROCURONIUM 50 mg B Braun** and monitoring your condition carefully it is unlikely that you will be given too much **ROCURONIUM 50 mg B Braun**. However, if this happens your anaesthetist or doctor will keep you breathing artificially (on a ventilator) until you can breathe on your own. You will be kept asleep while this takes place.

4. Possible side effects

ROCURONIUM 50 mg B Braun can have side effects.

Not all side effects reported for **ROCURONIUM 50 mg B Braun** are included in this leaflet. Should your general health worsen or if you experience any untoward effects after your operation when **ROCURONIUM 50 mg B Braun** was given to you, please consult your doctor, pharmacist or other healthcare professional for advice.

ROCURONIUM 50 mg B Braun can have side effects. If these side effects occur while you are under anaesthesia, they will be seen and treated by your anaesthetist.

Less frequent side effects:

- The medicine is too effective, or not effective enough.
- The medicine works for longer than expected.
- Lowering of blood pressure.
- Increase in heart rate.
- Pain near the site of injection.

- Allergic (hypersensitivity) reactions (such as difficulty in breathing, collapse of circulation and shock).
- Wheezing of the chest.
- Muscle weakness.
- Swelling, a rash or redness of the skin.
- Sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles.

Frequency unknown:

- Kounis syndrome which is a sudden allergic reaction which can cause chest pain and blocking of the arteries.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ROCURONIUM 50 mg B Braun

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

- Keep in original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ROCURONIUM 50 mg B Braun is and what it is used for

The active substance is: Rocuronium bromide.

Each ml **ROCURONIUM 50 mg B Braun** contains 10 mg rocuronium bromide.

The other ingredients are: Gluconolactone, sodium acetate trihydrate, sodium citrate (pH adjustment), water for injections

What ROCURONIUM 50 mg B Braun looks like and contents of the pack ROCURONIUM 50 mg B Braun , Intravenous

Clear solution free from visible particles

pH of the solution: 3.8 to 4.2

Osmolality: 270– 310 mOsmol/kg.

ROCURONIUM 50 mg B Braun = 5 mL: Cartons containing 20 x 5 mL colourless glass ampoules each of which contains 50 mg rocuronium bromide in aqueous solution.

HOLDER OF THE CERTIFICATE OF REGISTRATION

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