

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

Solution for injection in vials

(Sugar free)

Read all of this leaflet carefully before you start taking ROCURONIUM BROMIDE

INJECTION, 50 mg/5 mL RBC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC 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 is and what it is used for.
2. What you need to know before you use ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC
3. How to use ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC
4. Possible side effects.
5. How to store ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC
6. Contents of the pack and other information.

1. What ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC is and what it is used for

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC is one of a group of medicines called muscle relaxants.

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC relaxants are used during an operation

as part of the general anesthesia. When you have an operation, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC can also be used in the Intensive Care Unit to keep your muscles relaxed.

2. What you need to know before you take ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

Do not take ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC:

Do not use this medicine and tell your doctor or pharmacist if:

If you are hypersensitive (allergic) to rocuronium, the bromide ion or any of the other ingredients of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC.

There is insufficient data to support the use of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC in babies (0 to 1 month).

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC 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 with ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

Talk to your anaesthetist before you receive this medicine:

- if you are allergic to muscle relaxants
- if you have had kidney, heart, liver, or gall bladder disease
- if you have had diseases affecting nerves and muscles
- if you have fluid retention (oedema).

Tell your doctor if any of these applies to you.

- if you have a history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles).

Some conditions may influence the effects of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC — for example:

- low calcium levels in the blood
- low potassium levels in the blood
- high magnesium levels in the blood
- low levels of protein 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
- over-breathing leading to too little carbon dioxide in the blood (alkalosis)
- general ill-health
- burns
- being very overweight (obesity)
- very low body temperature (hypothermia).

If you have any of these conditions, your anaesthetist will take it into account when deciding the correct dose of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC for you.

Children and Elderly

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC cannot be used in children (new-borns and elderly) due to lack of information.

Taking other medicines with ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC:

Tell your anaesthetist if you are taking other medicines or have recently taken them. This includes medicines or herbal products that you have bought without a prescription. ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC may affect other medicines or be affected by them.

Medicines which increase the effect of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC:

- certain antibiotics
- certain medicines for heart disease or high blood pressure (*water tablets, calcium channel 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.

Medicines which decrease the effect of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC:

- certain medicines for epilepsy
- calcium chloride and potassium chloride
- certain protease inhibitors called gabexate and ulinastatin.

In addition, you may be given other medicines before or during surgery which can alter the effects of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC. ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC may make certain anaesthetics work more quickly. Your anaesthetist will take this into account when deciding the correct dose of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC for you.

Pregnancy, breast feeding and fertility

Use in pregnancy and breast feeding

If you are pregnant or breastfeeding inform your doctor or other healthcare professional. No clinical data on pregnancy are available.

Animal studies did not give any harmful effects with pregnancy

Animal studies have shown insignificant levels of rocuronium bromide in breast milk.

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 BROMIDE INJECTION, 50 mg/5 mL RBC.

Do not drive or use any tools or machines if you feel tired or sleepy from the treatment with ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC.

Important information about some of the ingredients of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How to take ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

Do not share medicines prescribed for you with any other person.

Always take ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dose:

Your anaesthetist will work out the dose of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC you need based on:

- the type of anaesthetic
- the expected length of the operation
- other medicines you are taking
- your state of health.

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

How ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC is given ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC will be given to you by your anaesthetist. ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC is given intravenously (into a vein), either as single injections or as a continuous infusion (a drip).

If you take more ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC than you should -

As your anesthetist will be monitoring your condition carefully it is unlikely that you will be given too much ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC. However, if this happens, your anesthetist will keep you breathing artificially (on a ventilator) until you can breathe on your own.

You will be kept asleep while this takes place.

If you missed a dose of ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

If you forget a dose, if it is nearly time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC can have side effects.

Not all side effects reported for ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC.

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC, please consult your doctor, pharmacist, or other healthcare professional for advice.

Like all medicines ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC can cause side effects, although not everybody gets them. If you're worried, talk to a doctor or pharmacist.

Frequencies are categorized: Frequent (very common and common), Less frequent (uncommon, rare and vert rare), Frequency not known indicates the (not known information or cannot estimated

from the available data).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice or experience any of the following:

Frequent side effects:

- Lowering of blood pressure
- The medicine is too effective, or not effective enough
- The medicine works for longer than expected
- Pain near the site of injection.
- Rigid muscles, high fever, fast heart rate and rapid breathing
- Prolonged stay in the postanesthesia care

Less Frequency side effects:

- Allergic (*hypersensitivity*) reactions (such as difficulty in breathing, collapse of the circulation and shock)
- Swelling, a rash or redness of the skin.
- Muscle weakness
- Increase in heart rate
- Wheezing of the chest
- Fluid collects under your face skin

•Frequency Not known side effects:

Severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction).

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 the “6.04 Adverse Drug reaction Reporting Form” found online under SAHPRA’s publications:

<https://www.sahpra.org.za/publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC is stored in the hospital. Store in the refrigerator at 2 to 8 °C.

Do not use ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC after the expiry date stated on the label.

Store all medicines out of reach of children.

Do not use ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC when you notice that the solution contains particles or is not clear.

6. Contents of the pack and other information

What ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC contains: The active substance is Rocuronium bromide.

Glacial Acetic Acid

Nitrogen

Sodium Acetate Trihydrate

Sodium Chloride

Sodium Hydroxide

Water for Injection

ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC –

ROCURONIUM BROMIDE INJECTION 50 mg/5 mL RBC is a glass vial closed with an uncoated rubber stopper and sealed with Aluminium seals assembled with a plastic button.

10 vials of 5 mL are packed into a printed carton along with a printed patient information leaflet.

Applicant: RBC PHARMACEUTICALS (PTY) LTD
Product Name: ROCURONIUM BROMIDE INJECTION, 50 mg/5 mL RBC
Dosage form and strength: Injection (50 mg/ 5mL)

MODULE 1
1.3.2.1.1
Submitted Date: 23.07.2025

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

RBC PHARMACEUTICALS (PTY)LTD
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