PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ROCURONIUM 50 IV BIOTECH, 10 mg/mL, Injection

Rocuronium bromide

Sugar free

Read all of this leaflet carefully before you are administered ROCURONIUM 50 IV BIOTECH.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.

What is in this leaflet

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

1. What ROCURONIUM 50 IV BIOTECH is and what it is used for

ROCURONIUM 50 IV BIOTECH contains rocuronium bromide, one of 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. This makes it easier for the surgeon to perform the operation.

Normally, your nerves send messages called impulses to your muscles. ROCURONIUM 50 IV BIOTECH acts by blocking these impulses so that your muscles relax.

Because your breathing muscles also relax, you will need help to breathe (artificial ventilation) during and after

your operation until you can breathe on your own again.

ROCURONIUM 50 IV BIOTECH may also be used as an adjunct in the Intensive Care Units (ICU) to keep your muscles relaxed (e.g. to ease the insertion of a tube into your trachea (windpipe)), for short term use.

2. What you need to know before you are administered ROCURONIUM 50 IV BIOTECH

ROCURONIUM 50 IV BIOTECH should not be administered to you:

- If you are hypersensitive (allergic) to rocuronium bromide, the bromide ion or any of the other ingredients of ROCURONIUM 50 IV BIOTECH (see section 6).
- Safety in pregnancy and breastfeeding has not been established (see section 2, "Pregnancy, breastfeeding and fertility").

ROCURONIUM 50 IV BIOTECH should not be used in newborn babies (0 to 1 month) and is not recommended in the facilitation of mechanical ventilation in the Intensive Care Units (ICU) in children and elderly patients (older than 65 years)

Tell your anaesthetist if this applies to you or the patient.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you are allergic to muscle relaxants.
- if you have had kidney, heart, liver or gall bladder disease.
- if you have fluid retention (oedema).
- if you take or used corticosteroids (medicines for inflammation). Myopathy (a disease of muscle tissue) may occur if these medicines are used together with ROCURONIUM 50 IV BIOTECH.
- if you have a history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles).

Tell your anaesthetist if any of these applies to you.

Some conditions may influence the effects of ROCURONIUM 50 IV BIOTECH:

- if you have had diseases affecting nerves and muscles (neuromuscular diseases, e.g. polio, myasthenia gravis or Eaton-Lambert syndrome).
- very low body temperature (hypothermia).
- being very overweight (obesity).
- if you had burnt your skin.
- low potassium levels in the blood (hypokalaemia). Some causes may be severe vomiting, diarrhoea or diuretic therapy.
- high magnesium levels in the blood (hypermagnesaemia).
- low calcium levels in the blood (hypocalcaemia).
- low levels of protein in the blood (hypoproteinaemia).
- loss of too much water from the body, for example by being sick, diarrhoea or sweating (dehydration).
- an increased amount of acids in the blood (acidosis).
- an increased amount of carbon dioxide in the blood (hypercapnia).
- if you suffer from excessive loss of weight (cachexia).

If you are suffering from any of these conditions, your anaesthetist will take this into account when deciding on the correct dose of ROCURONIUM 50 IV BIOTECH for you.

Prolonged paralysis and/or muscle weakness may occur in some patients (see section 4, “Possible side effects”). You will be carefully observed in hospital, during and after the operation.

Children and elderly

There is inadequate data to support the use of ROCURONIUM 50 IV BIOTECH in neonates (0 to 1 month). ROCURONIUM 50 IV BIOTECH should not be used for the facilitation of mechanical ventilation in the Intensive Care Unit (ICU) in paediatric and elderly patients due to a lack of data on safety and efficacy (see

"ROCURONIUM 50 IV BIOTECH should not be administered to you").

The same warnings and precautions as for adults should be taken into consideration.

Other medicines and ROCURONIUM 50 IV BIOTECH

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please tell your doctor or pharmacist if you are taking, or have recently taken or used:

Medicines which increase the effect of ROCURONIUM 50 IV BIOTECH:

- certain anti-inflammatory medicines (corticosteroids), such as dexamethasone in the long-term use for asthma or inflammation
- certain antibiotics, such as aminoglycosides, lincomycin, clindamycin, tetracyclines, high doses of metronidazole and penicillins
- certain medicines for heart disease or high blood pressure (diuretics (water tablets), calcium channel blockers, beta-blockers and quinidine)
- medicines for manic depressive illness (bipolar disorder)
- local anaesthetics such as lidocaine or bupivacaine
- certain medicines used to treat malaria (quinine)
- magnesium salts (laxatives or diet supplements).

Medicines which decrease the effect of ROCURONIUM 50 IV BIOTECH:

- certain medicines used for epilepsy treatment (such as phenytoin, carbamazepine)
- calcium chloride and potassium chloride
- noradrenaline (to increase and maintain blood pressure in limited, short-term serious health situations)
- azathioprine (controls rheumatoid arthritis)
- theophylline (to treat asthma and chronic obstructive pulmonary disease)
- certain protease inhibitors, such as gabexate and ulinastatin (medicines used for the treatment or prevention

of a viral infection)

- neostigmine or pyridostigmine (medicines used for the treatment of myasthenia gravis).

In addition, you may be given other medicines before or during surgery which can alter the effects of ROCURONIUM 50 IV BIOTECH. These include certain anaesthetics (such as local anaesthetics, general or inhalational anaesthetics), other muscle relaxants (such as suxamethonium), and medicines which reverse the effects of ROCURONIUM 50 IV BIOTECH.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before ROCURONIUM 50 IV BIOTECH is administered to you.

ROCURONIUM 50 IV BIOTECH should not be administered if you are pregnant or breastfeeding, as safety of its use in pregnancy and breastfeeding have not been established.

ROCURONIUM 50 IV BIOTECH may be given to you if you are having a Caesarean section.

There is no data available on fertility with ROCURONIUM 50 IV BIOTECH.

Driving and using machines

ROCURONIUM 50 IV BIOTECH can significantly affect your ability to drive a vehicle or to use machines (see section 4, “Possible side effects”). Do not drive a vehicle or use potentially dangerous machines during the first 24 hours.

Ask a responsible adult to take you home after your treatment. Ask your doctor when you can start driving and using machines again.

It is not always possible to predict to what extent ROCURONIUM 50 IV BIOTECH may interfere with the

daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ROCURONIUM 50 IV BIOTECH affects them.

ROCURONIUM 50 IV BIOTECH contains sodium

ROCURONIUM 50 IV BIOTECH contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How ROCURONIUM 50 IV BIOTECH will be administered to you

Your anaesthetist will work out the dose of ROCURONIUM 50 IV BIOTECH you need based on:

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

Adults:

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

Use in children and adolescents (0 to <18 years of age):

ROCURONIUM 50 IV BIOTECH may be given to infants (28 days to 23 months), children (2 to 14 years) and adolescents (12 to 18 years). There is inadequate data to support the use of ROCURONIUM 50 IV BIOTECH in neonates (0 to 1 month).

The dose and its effect in children are similar to those in adults, but the anaesthetist will adjust the dose according to the needs of your child. Your doctor will consider if higher infusion rates might be necessary.

Method and route of administration

You will not be expected to give yourself ROCURONIUM 50 IV BIOTECH. It will be given to you by a person

who is qualified to do so. ROCURONIUM 50 IV BIOTECH will be given to you by your anaesthetist.

ROCURONIUM 50 IV BIOTECH is given intravenously (into a vein), either as single injections or as a continuous infusion (a drip over a longer period).

Your doctor will tell you how long your treatment with ROCURONIUM 50 IV BIOTECH will last.

If you have the impression that the effect of ROCURONIUM 50 IV BIOTECH is too strong or too weak, tell your doctor or pharmacist.

If you are administered more ROCURONIUM 50 IV BIOTECH than you should

Since a health care provider will administer ROCURONIUM 50 IV BIOTECH, he/ she will control the dosage. However in the event of overdosage, your doctor will manage the overdosage. Your anaesthetist will keep you breathing artificially (on a ventilator) until you can breathe on your own. You may be kept asleep while this takes place.

Your anaesthetist will carefully monitor your pulse rate, temperature, rate of breathing and blood pressure while you are treated with ROCURONIUM 50 IV BIOTECH, therefore it is unlikely that you will be given too much ROCURONIUM 50 IV BIOTECH.

If a dose ROCURONIUM 50 IV BIOTECH is missed

Since your anaesthetist will administer ROCURONIUM 50 IV BIOTECH, it is unlikely that the dose will be missed.

4. Possible side effects

ROCURONIUM 50 IV BIOTECH can have side effects.

Not all side effects reported for ROCURONIUM 50 IV BIOTECH are included in this leaflet. Should your general health worsen after receiving ROCURONIUM 50 IV BIOTECH, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using ROCURONIUM 50 IV BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ROCURONIUM 50 IV BIOTECH. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side-effects:

- weakness or loss of movement (paralysis) and reduced muscle tone without other obvious cause
- irregular heartbeat (dysrhythmia) or increase in heart rate (tachycardia)
- lowering of blood pressure (hypotension)
- increase in blood pressure (hypertension)
- failure of circulation (circulatory collapse and shock)
- flushing
- wheezing of the chest (bronchospasm)
- hiccups, feeling sick (nausea) or being sick (vomiting)
- skin hives, rash or redness of the skin, itching, swelling
- muscle weakness, which may be worse if you have been treated with corticosteroids. See “Other medicines and ROCURONIUM 50 IV BIOTECH”
- the medicine is too effective, or not effective enough
- pain and redness at the injection site
- increased level of histamine in the blood
- the medicine works for longer than expected (prolonged effect of muscle relaxation/ prolonged

neuromuscular block)

Side effects with unknown frequency:

- dilated pupils (mydriasis) or fixed pupils that do not change size with light or other stimuli
- severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction).
- breathing (respiratory) failure, temporary cessation of breathing (apnoea)
- sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles (malignant hyperthermia).

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ROCURONIUM 50 IV BIOTECH.

5. How to store ROCURONIUM 50 IV BIOTECH

Store all medicines out of reach of children.

ROCURONIUM 50 IV BIOTECH is stored in the hospital, in a refrigerator (2 to 8 ºC). Do not freeze. Protect from light.

Keep vial in outer carton until required for use.

After dilution:

Since ROCURONIUM 50 IV BIOTECH does not contain any preservative, it should be used immediately after first opening the container and any unused solution should be discarded.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user/administrator 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 ROCURONIUM 50 IV BIOTECH if you notice that the solution is not clear or free from particles.

Do not use after the expiry date printed on the outer carton.

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

6. Contents of the pack and other information

What ROCURONIUM 50 IV BIOTECH contains

The active substance is rocuronium bromide.

Each 1 mL contains 10 mg rocuronium bromide. Each 5 mL vial contains 50 mg rocuronium bromide.

The other ingredients are sodium acetate (E262) (for pH adjustment), sodium chloride, glacial acetic acid (E260) (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injection.

No preservative has been added.

What ROCURONIUM 50 IV BIOTECH looks like and contents of the pack

ROCURONIUM 50 IV BIOTECH is a clear, colourless to yellow or orange solution.

ROCURONIUM 50 IV BIOTECH is filled into a 5 mL clear Type I glass vial with 13 mm bromobutyl rubber stopper and aluminium flip-off seal with green colour button.

Pack size: 12 x 5 mL, 10 x 5 mL, or 1 x 5 mL vials per outer carton.

Not all pack sizes may be marketed.

Holder of certificate of Registration

Biotech Laboratories (Pty) Ltd.

400 16th Road

Ground Floor, Block K West, Central Park

Randjespark

Midrand, 1685

Tel no: +27 (0) 11 848 3050

This leaflet was last revised in

18 March 2026

Registration number

44/17.1/0188

Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.