

Ranbaxy Pharmaceuticals (Pty) Ltd

MUSCURON 4 mg/vial

INJECTION for IV injection or by IV infusion (Vecuronium bromide)

Patient Information Leaflet

SCHEDULING STATUS

S4

MUSCURON 4 mg/mL

Vecuronium bromide

Contains sugar (mannitol 38,80 mg per vial)

Read all of this leaflet carefully before you start taking MUSCURON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist.

What is in the leaflet

1. What **MUSCURON** is and what it is used for
2. What you need to know before you take **MUSCURON**
3. How to take **MUSCURON**
4. Possible side effects
5. How to store **MUSCURON**
6. Contents of the pack and other information

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INJECTION for IV injection or by IV infusion (Vecuronium bromide)

1. What MUSCURON is and what it is used for

MUSCURON contains the active substance vecuronium bromide. **MUSCURON** is used as a muscle relaxants during anaesthesia and surgery.

2. What you need to know before you take MUSCURON

MUSCURON should not be administered to you:

- If you are hypersensitive (allergic) to vecuronium bromide or bromide ion or any of the ingredients of **MUSCURON** (listed in **section 6**).
- The safety and efficacy of **MUSCURON** injection in children 3 months or younger have not been established.
- The safety in pregnancy and lactation has not been established.

Warnings and precautions

Tell your doctor or health care provider before being given **MUSCURON**.

- if you have a heart disease or an underlying disease that affects your blood circulation
- if you are allergic to **MUSCURON** or any muscle relaxants.
- if you have diseases affecting nerves and muscles (poliomyelitis, myasthenia gravis, Eaton Lambert syndrome)
- **MUSCURON** can cause respiratory paralysis.

Some conditions may influence the effects of MUSCURON

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- if you suffer from severe kidney disease.
- if you are overweight (obesity)
- if your body temperature drops below normal (hypothermia).
- if you have low levels of potassium in the blood (hypokalaemia, caused by severe vomiting and diarrhoea).
- if you have burns.
- if you have high levels of magnesium in the blood. (hypermagnesaemia).
- if you have low levels of calcium in the blood after blood transfusion.
- if you have low levels of proteins in the blood.
- loss too much water from the body (dehydration)
- if you have too much acid the blood or body tissue (acidosis)
- an increase level of carbon dioxide in the blood (hypercapnia)
- if you have a disease that causes extreme weight loss and muscle wasting (cachexia).

Children and adolescents

The safety and efficacy of Muscuron injection in children 3 months or younger have not been established.

Other medicines and MUSCURON

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

Medicines which increases the effect of Vecuronium:

- certain medicines used to make you sleep during surgery (anaesthetics; for example ether, isoflurane, methoxyflurane, cyclopropane, halothane, enflurane, suxamethonium)
- certain medicines to treat bacterial infections (antibiotics; for example aminoglycosides, lincosamide and polypeptide antibiotics, acylamino-penicillin antibiotics)
- medicines which increase the amount of urine (diuretics or water tablets)
- medicines used for the treatment of heart disease or high blood pressure (calcium channel blockers, beta-blockers and quinidine)
- medicines used to treat mania, manic depressive illness or depression (lithium salts)
- certain medicines used to treat stomach ulcers, heartburn or acid reflux (cimetidine)
- some laxatives such as magnesium salts
- long-term concomitant use of certain anti-inflammatory medicines (corticosteroids)
- certain medicines for reducing pain (local anaesthetics; for example lidocaine)
- short-term concomitant use of certain medicines used for epilepsy (phenytoin).

Medicines which decrease the effect of MUSCURON

- certain medicines used for epilepsy (for example phenytoin or carbamazepine)
- calcium chloride and potassium chloride.

Effect of MUSCURON on other medicines

- **MUSCURON** may make certain anaesthetics (for example lidocaine) work more quickly.

Pregnancy, breastfeeding and fertility

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The safety of **MUSCURON** injection during pregnancy or lactation has not been established.

Driving and using machines

Do not operate potentially dangerous machinery or drive a car within 24 hours after receiving **MUSCURON**.

MUSCURON contains mannitol (38,80 mg per vial)

MUSCURON contains mannitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before being given this medicine.

3. How to take MUSCURON

You will not be expected to give yourself MUSCURON. It will be given to you by a person who is qualified to do so.

MUSCURON injection will be administered in a vein by a medical professional during surgery.

The dose will depend on your body weight and the response required by your doctor.

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If you take more MUSCURON than you should

Since a health care provider will administer **MUSCURON**, he / she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

If you forget to take MUSCURON

Since a health care provider will administer **MUSCURON**, it is unlikely that the dose will be missed.

4. Possible side effects

MUSCURON can have side effects.

Not all side effects reported for **MUSCURON** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **MUSCURON**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MUSCURON**. You may need urgent medical attention or hospitalisation.

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Tell your doctor if you notice any of the following:

Uncommon/Less frequent side effects:

- muscle weakness or paralysis
- failure of circulation (circulatory collapse and shock)
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- rapid swelling under the skin (angioneurotic oedema)
- rash or redness of the skin (erythematous rash)
- pain near the site of injection
- airway complication of anaesthesia
- longer than usual muscle disorder usually seen after the use of **MUSCURON** in combination with steroids (corticosteroids including an inflammatory effect) in severe ill patients (steroid myopathy).

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 “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 **MUSCURON**.

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5. How to store MUSCURON

- Store at or below 25 °C.
- Reconstituted solution containing 2 mg/mL of **MUSCURON** is stable for 24 hours, stored at or below 25°C.
- Store all medicines out of reach of children.
- Protect from light. Do not freeze.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MUSCURON contains

The active substance is vecuronium bromide

The other ingredients are: mannitol, citric acid, disodium hydrogen phosphate, sodium hydroxide, phosphoric acid, water for injection.

What MUSCURON looks like and contents of the pack

Unreconstituted: white cake of lyophilized mass

Reconstituted solution is clear and colourless.

2 mL clear Type I glass vial with grey rubber stopper and electric blue flip-top aluminium seal

Holder of Certificate of Registration

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South Africa

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