Product Name: Esmeron	Component: English Patient Information Leaflet Date Implemented: 02 February 2024

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ESMERON® 50 mg = 5 mL

ESMERON® 100 mg = 10 mL

Solution for injection in vials

rocuronium bromide

Read all of this leaflet carefully before you are given ESMERON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ESMERON has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ESMERON is and what it is used for

ESMERON is one of 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.

ESMERON can also be used in the Intensive Care Unit to keep your muscles relaxed.

2. What you need to know before ESMERON is given

You should not receive ESMERON

If you are hypersensitive (allergic) to rocuronium, the bromide ion or any of the other ingredients of ESMERON.

There is insufficient data to support the use of ESMERON in babies (0 to 1 month).

ESMERON 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

Special care should be taken with ESMERON

Your anaesthetist needs to know before you receive ESMERON:

- 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).

Tell your anaesthetist if any of these apply to you.

Some conditions may influence the effects of ESMERON e.g.

- 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 e.g. 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 are suffering from any of these conditions your anaesthetist will take this into account when deciding on the correct dose of ESMERON for you.

Using other medicines with ESMERON

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ESMERON with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Medicines which increase the effect of ESMERON:

- 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.

Medicines which decrease the effect of ESMERON:

- Certain medicines for epilepsy.
- Calcium chloride and potassium chloride.
- Certain protease inhibitors called gabexate and ulinastatin.

In addition, you may be given other medicine before or during surgery which can alter the effects of ESMERON. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of ESMERON.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, inform your doctor, anaesthetist or other healthcare professional.

Driving and using machinery

Your doctor will inform you when it is safe to drive and operate potentially dangerous machinery after you have been administered ESMERON.

Do not drive or use any tools or machines if you feel tired or sleepy from the treatment with ESMERON.

3. How ESMERON is administered

Dosage

The doctor will determine the dose. You will be given ESMERON before and/or during a surgical procedure. During the procedure it will be checked whether ESMERON is still working. You may be given additional doses if they are needed.

Method and route of administration

ESMERON will be given to you by your anaesthetist. ESMERON is given intravenously (into the vein), either as single injections or as a continuous infusion (a drip).

If you receive more ESMERON than you should

As your anaesthetist will be monitoring your condition carefully it is unlikely that you will be given too much ESMERON. However if this happens your anaesthetist 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 have any further questions on the use of ESMERON, ask your doctor or anaesthetist.

4. Possible side effects

ESMERON can have side effects. If these side effects occur while you are under anaesthesia, they will be seen and treated by your anaesthetist.

Frequent side effects: (up to 1 in 100 people given ESMERON are affected)

- 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.

Less frequent side effects: (< 1 in 10 000 people given ESMERON are affected)

- 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.
- Dilated pupils (mydriasis) or fixed pupils.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist 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 ESMERON.

5. How to store ESMERON

Store all medicines out of reach of children.

ESMERON is stored in the hospital. Store in the refrigerator at 2 to 8 °C.

ESMERON may be stored at a temperature not exceeding 30 °C, for a maximum period of 12 weeks. After first removal from the refrigerator, the 12-week shelf life applies. After opening of the container the solution is chemically stable for 24 hours at room temperature. Since ESMERON does not contain a preservative, any unused solution should be discarded.

Do not use ESMERON after the expiry date stated on the label.

Do not use ESMERON when you notice that the solution contains particles or is not clear.

6. Contents of the pack and other information

What ESMERON contains

The active substance is: Rocuronium bromide.

Each mL ESMERON contains 10 mg rocuronium bromide.

The other ingredients are: glacial acetic acid, sodium acetate, sodium chloride and water for injection.

Each mL ESMERON contains 1,72 mg sodium. No preservative has been added.

What ESMERON looks like and contents of the pack

ESMERON 50 mg = 5 mL: 5 mL vial containing a clear, colourless to faintly yellow, aqueous solution.

ESMERON 100 mg = 10 mL: 10 mL vial containing a clear, colourless to faintly yellow, aqueous solution.

ESMERON 50 mg = 5 mL: Cartons containing 10 x 5 mL clear, glass vials each of which contains 50 mg rocuronium bromide in aqueous solution.

ESMERON 100 mg = 10 mL: Cartons containing 10 x 10 mL clear, glass vials each of which contains 100 mg rocuronium bromide in aqueous solution.

Holder of Certificate of Registration

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Registration numbers

ESMERON 50 mg = 5 mL: 30/17.1/0192

ESMERON 100 mg = 10 mL: 30/17.1/0193