Package leaflet: Information for the user

ESMERON®
10 mg/ml
solution for injection

ROCURONIUM BROMIDE

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your anaesthetist or other doctor.
- If you get any side effects, talk to your anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. See section 4.

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 Esmeron is stored
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 drugs 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. Esmeron 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.

During the operation your anaesthetist will keep a check on the effect of the muscle relaxant, and if necessary will give you some more. At the end of surgery, the effects of the drug are allowed to wear off and you will start breathing on your own. Sometimes the anaesthetist will give you another drug to help speed this up.

Esmeron can also be used in Intensive Care Units to keep your muscles relaxed.

2. What you need to know before Esmeron is given

You should not receive Esmeron
• **if you are allergic** (*hypersensitive*) to rocuronium, the bromide ion or any of the other ingredients of this medicine (listed in section 6).

—> **Tell your anaesthetist if this applies to you.**

Warnings and precautions
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 you have or have had the following:

a rare tumour of the adrenal glands (phaeochromocytoma); this may increase the risk of severe high blood pressure

—> **Tell your anaesthetist 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 Esmeron — 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 Esmeron for you.

Children and Elderly
Esmeron can be used in children (newborns and adolescence) and elderly but your anaesthetist should first assess your medical history.

Other medicines and Esmeron
—> **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. Esmeron may affect other medicines or be affected by them.

Medicines which increase the effect of Esmeron:
• 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 Esmeron:
• 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 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 and breast feeding
—>**Tell your anaesthetist if you are pregnant or might be pregnant, or if you are breast feeding.**
Your anaesthetist may still give you Esmeron, but you need to discuss it first. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your anaesthetist or other doctor for advice before taking this medicine. Esmeron may be given to you if you are having a Caesarean section.
Breastfeeding should be suspended 6 hours after use of this medicine.

Driving and using machines
Do not drive or use machines until advised it is safe to do so. Because Esmeron is given as part of a general anaesthetic, you may feel tired, weak or dizzy for some time afterwards. Your anaesthetist will be able to advise you on how long the effects are likely to last.

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

3. How Esmeron is given

Dose
Your anaesthetist will work out the dose of Esmeron you need based on:
• the type of anaesthetic
• the expected length of the operation
• other drugs you are taking
• your state of health.
The normal dose is 0.6 mg per kg body weight and the effect will last 30–40 minutes.

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

If you are given more Esmeron than you need
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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.

Uncommon side effects
(may affect up to 1 in 100 people)
• the drug is too effective, or not effective enough
• the drug works for longer than expected
• lowering of blood pressure
• increase in heart rate
• pain near the site of injection.

Very rare side effects
(may affect up to 1 in 10,000 people)
• allergic (*hypersensitivity*) reactions (such as difficulty in breathing, collapse of the circulation and shock)
• wheezing of the chest
• muscle weakness
• swelling, a rash or redness of the skin.

Not known
(frequency cannot be estimated from the available data)

- severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction).
- dilated pupils (mydriasis) or fixed pupils that do not change size with light or other stimuli.

If any of the side effects gets serious
Or if you notice any side effects not listed in this leaflet:
—> **Tell your anaesthetist or other doctor.**

Reporting of side effects
If you get any side effects, talk to your anaesthetist or other doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How Esmeron is stored

Esmeron is stored in the hospital. Store in the refrigerator at 2-8°C. The product can be stored outside the refrigerator at a temperature of up to 30°C for a maximum of 3 months. The product may be placed in and out the refrigerator at any point(s) during the 36 month shelf life, but the total storage time outside the refrigerator must not exceed 3 months. The storage period may not exceed the labeled shelf life.

The hospital will keep Esmeron according to the correct storage conditions, and will ensure that it's in its expiry date.

6. Contents of the pack and other information

What Esmeron contains
The active substance of Esmeron is rocuronium bromide 10 mg/ml.
The other ingredients are sodium acetate (E262), sodium chloride, acetic acid (E260) and water for injections. Each millilitre (ml) of Esmeron contains 1.64 mg of sodium. No preservative has been added.

What Esmeron looks like and contents of the pack
Esmeron is a colourless to slightly yellow/brown solution for injection. It is available in vials containing 25 mg (10 vials per pack), 50 mg (10 vials per pack) or 100 mg (10 vials per pack) of rocuronium bromide.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, UK

Manufacturer: Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Problems reading this leaflet?
To listen to or request a copy of this leaflet in Braille, large print or audio, please call, free of charge:
0800 198 5000 (UK only).
Please be ready to give the following information:
Product name: Esmeron
Reference Number: PL 53095/0001
This is a service provided by the Royal National Institute of the Blind.

This leaflet was last revised in February 2026.

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