ESMERON®
10 mg/ml
Solution for Injection/Infusion
ROCURONIUM BROMIDE

INFORMATION FOR THE PATIENT

Read all of this leaflet carefully before you are given this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your anaesthetist.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your anaesthetist or doctor.

In this leaflet:

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 the general anesthetic. When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

Normally the nerves send messages called *impulses* to your muscles. Esmeron acts by blocking these impulses so that the muscles relax. Because the 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 can 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 Unit to keep your muscles relaxed.

2. 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 Esmeron.
  → Tell your anaesthetist if this applies to you.

Take special care with Esmeron
Your anaesthetist needs to know 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** *(e.g. poliomyelitis, myasthenia gravis)*
- 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

- 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 *(acidosis)*
- loss of too much water from the body, for example by being sick, diarrhoea or sweating *(dehydration)*
- over-breathing leading to too little carbon dioxide in the blood *(alkalosis)*
- general ill-health
- burns
- being very overweight *(obesity)*

If you have any of these conditions your anaesthetist will take it into account when deciding the correct dose of Esmeron for you.

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 for **bipolar disorder** *(lithium salts)*
- certain medicines used to treat **malaria** *(quinine)*
- certain medicines **used to make you sleep** during surgery *(anesthetics)*
- certain medicines which cause **increased volume of urine** *(diuretics)*
- certain **local anaesthetics** *(lidocaine, bupivacaine)*
- certain medicines for **epilepsy** during an operation *(phenytoin)*
- certain medicines used to **induce short-term muscle relaxation** in anesthesia and intensive care *(suxamethonium)*

Medicines which decrease the effect of Esmeron:

- long term use of medicines for **epilepsy** *(phenytoin and carbamazepine)*

- certain **protease inhibitors** called gabexate, ulinastatin
- acetylcholinesterase inhibitors, medicines for the **treatment of myasthenia gravis** *(e.g. neostigmine, edrophonium, pyridostigmine, aminopyridine derivatives)*

In addition, you may be given other medicines before or after 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 suspect that you are pregnant, or if you are breast-feeding,
Your anaesthetist may still give you Esmeron, but you need to discuss it first. 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

The 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 0.6mg per kg body weight and the effect lasts 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).

Children/elderly

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

Overdose
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 forget to take Esmeron
Not applicable

4. Possible side-effects

Like all medicines, Esmeron can have 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
(up to 1 in 100 people given Esmeron are affected)
- 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
(less than 1 in 10,000 people given Esmeron are affected)
- allergic (*hypersensitivity*) reactions (such as difficulty in breathing, collapse of the circulation and shock)
- wheezing of the chest
- muscle weakness
- swelling, a rash or wheals or redness of the skin
- Long term muscle dysfunction usually observed when Esmeron and anti-inflammatory medicines (corticosteroids are used in the Intensive Care Unit at the same time in critically ill patients (steroid myopathy)
- airway complication of anesthesia

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 its size with light or other stimuli

If any of these side effects get 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esmeron

Keep Esmeron out of sight and reach of children.

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

For single use only.

Do not use Esmeron after the expiry date stated on the label/carton.

Do not use Esmeron if you notice that the solution (or the diluted solution) contains particles or is not clear.

The diluted product should be used immediately.

6. Further information

What Esmeron contains
The active substance is: rocuronium bromide

Each ml Esmeron contains 10 mg rocuronium bromide.

Each 2.5 ml vial contains 25 mg rocuronium bromide.
Each 5 ml vial contains 50 mg rocuronium bromide.
Each 10 ml vial contains 100 mg rocuronium bromide

The other ingredients are: sodium acetate trihydrate, sodium chloride, glacial acetic acid, water for injections. Each millilitre (ml) Esmeron contains 1.64 mg sodium.

What Esmeron looks like and contents of the pack
Esmeron is a colourless to slightly yellow/brown solution for injection or infusion containing 10 mg/ml rocuronium bromide. It is available in vials containing 25 mg (10 vials per pack), 50 mg (10 vials per pack) and 100 mg rocuronium bromide (10 vials per pack).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Merck Sharp & Dohme Ireland (Human Health) Limited
Red Oak North
South County Business Park
Leopardstown
Dublin 18
Ireland

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

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