

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Esmeron?

Esmeron contains the active ingredient rocuronium bromide. Esmeron is one of a group of medicines called muscle relaxants. Esmeron is used during an operation as part of the general anaesthetic. When you have an operation, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation. For more information, see Section [1. Why am I using Esmeron?](#) in the full CMI.

2. What should I know before I use Esmeron?

Do not use if you have ever had an allergic reaction to Esmeron or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Esmeron?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Esmeron and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Esmeron?

- Esmeron will be given by a doctor. It will not be given to you until you are asleep from the anaesthetic.
  - It will be injected into a vein before and/or during an operation. It will be given as a single injection or continuous infusion.
- More instructions can be found in Section [4. How do I use Esmeron?](#) in the full CMI.

5. What should I know after having Esmeron?

Driving or using machines	<ul style="list-style-type: none"><li>• Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given Esmeron</li></ul>
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For more information, see Section [5. What should I know after having Esmeron?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Esmeron can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using Esmeron. When you get Esmeron, you can have some serious side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Esmeron. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Esmeron.**

**Where to find information in this leaflet:**

- [1. Why am I using Esmeron?](#)
- [2. What should I know before I use Esmeron?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Esmeron?](#)
- [5. What should I know after having Esmeron?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Esmeron?

**Esmeron contains the active ingredient rocuronium bromide.** Esmeron is one of a group of medicines called muscle relaxants.

**Esmeron is used during an operation as part of the 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 the nerves send messages to the muscles by impulses. Esmeron acts by blocking these impulses so the muscles are relaxed. Because the muscles needed for breathing also become relaxed you will need help with your breathing (artificial respiration) during and after your operation until you can breathe on your own. During the operation the effect of the muscle relaxant is constantly checked and if necessary some more drug is given. At the end of the operation the effects of Esmeron are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. Esmeron can also be used in Intensive Care to keep your muscles relaxed. Esmeron is not addictive.

### 2. What should I know before I use Esmeron?

#### Warnings

If you are going to have an operation it is important that you discuss the following points with your doctor, since it can influence the way Esmeron is given to you.

#### Do not use Esmeron if:

- you are allergic to rocuronium bromide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

#### Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - an allergy to muscle relaxants
  - kidney disease
  - liver or gallbladder disease
  - a heart disease
  - diseases affecting nerves or muscles
  - oedema (local or generalised swelling due to fluid)
- have any medical conditions that may affect how Esmeron works:
  - low potassium levels in the blood
  - high magnesium levels in the blood
  - low calcium levels in the blood
  - low levels of protein in the blood
  - dehydration
  - too much acid in the blood
  - too much carbon dioxide in the blood
  - general ill-health
  - overweight
  - burns

If you are suffering from any of these conditions your doctor will take this into account when deciding the correct dose of Esmeron for you.

- take any medicines for any other condition
- have allergies to any other medicines

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using Esmeron if you are pregnant or breast-feeding.

#### Children / Elderly

Esmeron can be used in term newborn infants (0-28 days), infants (28 days-23 months), children (2-11 years), adolescents (12-18 years) and elderly patients but your doctor should first assess your medical history.

Elderly (65 years and older) may be at an increased risk of residual paralysis.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Esmeron, and affect how it works.**

**Medicines that may increase the effect of Esmeron include:**

- anaesthetics (medicines used to make you sleep during surgery)
- long term concurrent use of corticosteroids (anti-inflammatory medicines) and Esmeron in the Intensive Care Unit
- antibiotics
- lithium (medicines used to treat bipolar disorder)
- quinidine, calcium channel blockers, beta-blockers and diuretics (fluid tablets) (medicines used to treat heart disease or high blood pressure)
- quinine (a medicine used to treat malaria)
- magnesium salts
- lidocaine (lignocaine) and bupivacaine hydrochloride (local anaesthetics)
- use of phenytoin (medicines used to treat epilepsy) during an operation

**Medicines that may reduce the effect of Esmeron include:**

- long term use of carbamazepine and phenytoin (medicines used to treat epilepsy)

**Medicines that have variable effect of Esmeron include:**

- other muscle relaxants

**Esmeron may influence the effects of the following medicines:**

- the effect of local anaesthetics (lidocaine) may be increased

You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

If you are taking magnesium sulfate to treat toxemia of pregnancy (preeclampsia), tell your doctor as the dose of Esmeron may need to be reduced.

Your doctor will have a complete list of medicines that may cause problems when used with Esmeron.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Esmeron.**

## 4. How do I use Esmeron?

**How much to use**

- The doctor will determine the dose. The usual dose is 0.6 mg rocuronium bromide per kg body weight and the effect lasts 30-40 minutes. During the operation your doctor will check whether Esmeron is still working. You may be given additional doses if they are needed.

**When to use Esmeron**

- Esmeron will be given by a doctor. It will not be given to you until you are asleep from the anaesthetic.
- It will be injected into a vein before and/or during an operation. It will be given as a single injection or continuous infusion.

**If you are given too much Esmeron**

As Esmeron doses are carefully worked out and are given by a doctor experienced in its use, it is extremely unlikely that you will be given too much Esmeron. However, if this does happen, your doctor will make sure that you continue breathing artificially until you can breathe on your own again.

Your doctor may speed-up your recovery by giving you a drug that reverses the effects of Esmeron.

## 5. What should I know after having Esmeron?

**Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Esmeron affects you.**

Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given Esmeron.

**Looking after your medicine**

Esmeron is stored in the hospital.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Less serious side effects**

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• flushing</li> <li>• pain at injection site</li> <li>• irritation at injection site</li> <li>• red skin rash or itchy rash</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

**Serious side effects**

Serious side effects	What to do
<p><b>Signs and symptoms of cardiovascular problems:</b></p> <ul style="list-style-type: none"> <li>• fast heartbeat</li> <li>• dizziness, light-headedness (low blood pressure)</li> </ul> <p><b>Signs and symptoms of muscle problems:</b></p> <ul style="list-style-type: none"> <li>• muscle weakness or paralysis</li> <li>• aching muscles or weakness, not caused by exercise</li> </ul> <p><b>Signs and symptoms of lung problems:</b></p> <ul style="list-style-type: none"> <li>• wheezing, coughing</li> <li>• difficulty breathing</li> </ul> <p><b>Signs and symptoms of allergic reactions:</b></p> <ul style="list-style-type: none"> <li>• rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting</li> <li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects after being discharged from the hospital.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing</li> <li>severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction)</li> </ul> <p><b>Signs and symptoms of problems in other organs:</b></p> <ul style="list-style-type: none"> <li>sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles</li> <li>Dilated pupils (mydriasis) or fixed pupils</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What Esmeron contains

<b>Active ingredient (main ingredient)</b>	rocuronium bromide
<b>Other ingredients (inactive ingredients)</b>	sodium acetate trihydrate sodium chloride glacial acetic acid water for injection

No preservative has been added.

**Do not take this medicine if you are allergic to any of these ingredients.**

#### What Esmeron looks like

Esmeron is clear, colourless to faintly yellow solution in a vial.

Esmeron 50 mg/5 mL injection is available in packs of 10 vials (AUST R 57063).

#### Who distributes Esmeron

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road, Macquarie Park NSW 2113, AUSTRALIA

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