

ROCURONIUM MYLAN

contains the active ingredient Rocuronium bromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ROCURONIUM MYLAN. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Rocuronium Mylan against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ROCURONIUM MYLAN is used for?

Rocuronium Mylan is one of a group of medicines called muscle relaxants.

Muscle relaxants are 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. Rocuronium Mylan 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 Rocuronium Mylan are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. Rocuronium Mylan can also be used in Intensive Care to keep your muscles relaxed.

Ask your doctor if you want any more information about this medicine.

Rocuronium Mylan is not addictive.

Before you are given Rocuronium Mylan

When you must not be given it

You must not be given Rocuronium Mylan if you have an allergy to:

- any medicine containing rocuronium bromide
- any of the ingredients listed at the end of this leaflet

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.

Rocuronium Mylan should not be given to a child under the age of one month.

The safety of administration of Rocuronium Mylan has not been established in children under the age of one month.

Before you are given it

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 Rocuronium Mylan is given to you.

Tell your doctor if you have or have had any 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)

Certain medical conditions may affect how Rocuronium Mylan 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 Rocuronium Mylan for you.

Rocuronium Mylan can be used in children (30 days to adolescence) and elderly but your doctor should first assess your medical history.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell them before you are given Rocuronium Mylan.

Taking other medicines

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

Some medicines may be affected by Rocuronium Mylan, or affect how well it works. These include:

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

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

If you are taking magnesium sulphate to treat toxemia of pregnancy (preeclampsia), tell

your doctor as the dose of Rocuronium Mylan may need to be reduced.

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

How Rocuronium Mylan is given

Rocuronium Mylan 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.

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 Rocuronium Mylan is still working. You may be given additional doses if they are needed.

Overdose

As Rocuronium Mylan 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 Rocuronium Mylan. 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 Rocuronium Mylan.

After having Rocuronium Mylan

Things to be careful of

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well when you have been given Rocuronium Mylan.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice the following and they worry you:

- flushing
- pain at injection site
- irritation at injection site
- red skin rash or itchy rash

Tell your doctor immediately if you notice any of the following:

- fast heart beat
- dizziness, light-headedness (low blood pressure)
- muscle weakness or paralysis
- aching muscles or weakness, not caused by exercise
- wheezing, coughing
- difficulty breathing
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing

- 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

These are serious side effects. You may need urgent medical attention or hospitalisation.

Storage

Rocuronium Mylan is stored in the hospital. It should be kept in the refrigerator at 2 - 8°C and not be frozen.

Rocuronium Mylan can be stored outside the refrigerator at a temperature up to 30°C for a maximum of 12 weeks. Once it has been kept outside, it must not be placed back into the refrigerator.

Product description

What it looks like

A vial containing a clear colourless to yellow or orange solution.

Rocuronium Mylan is available in two quantities: 50 and 100 mg.

Ingredients

Rocuronium Mylan contains 10 mg/mL of rocuronium bromide as the active ingredient.

It also contains:

- sodium acetate trihydrate
- sodium chloride
- acetic acid
- water for injections

No preservative has been added.

Sponsor

Alphapharm Pty Limited
30 The Bond, 30 - 34 Hickson Road
Millers Point, NSW 2000

Australian Registration Number:

AUST R 169872 ROCURONIUM MYLAN

rocuronium bromide 50mg/5mL injection vial

AUST R 170430 ROCURONIUM MYLAN

rocuronium bromide 100mg/10mL injection vial

This leaflet was prepared in January 2015.