• long term concurrent use of corticosteroids (anti- inflammatory medicines) and Rocuronium bromide 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 hydrochloride (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 toxaemia of pregnancy (preeclampsia), tell your doctor as the dose of Rocuronium bromide may need to be reduced.
Your doctor will have a complete list of medicines that may cause problems when used with Rocuronium bromide.

How Rocuronium bromide is given

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

Overdose

As Rocuronium bromide 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 bromide.
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 bromide.

After having Rocuronium bromide

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 bromide.

Side effects

Tell your doctor if you notice anything that is making you feel unwell.
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 heartbeat
• 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
• Sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles
• Severe allergic coronary blood vessels spasm (Kounis syndrome) resulting in chest pain (angina) or heart attack (myocardial infarction)
• Dilated pupils (mydriasis) or fixed pupils
These are serious side effects. You may need urgent medical attention or hospitalization.

What it looks like

A vial containing a is a clear, colourless to pale yellow solution for injection.
Rocuronium bromide is available in clear glass vials in packs of 10 vials

Ingredients

Rocuronium bromide contains 10 mg/mL of rocuronium bromide as the active ingredient. It also contains:
• water for injections
No preservative has been added

Storage : Store protected from light, at a temperature between 2°C to 8°C. Do not freeze.
Improper storage may deteriorate the product.
Medicine : Keep out of reach of children.

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For the use of a Registered Medical Practioner or a Hospital or a Laboratory or only.

℞ Rocuronium Bromide Injection IP

AMERICAN

Rocura 50

Injection

For IV Use Only

Composition :
Each ml contains :
Rocuronium Bromide IP 10mg
Water for Injections IP q.s.
This leaflet answers some common questions about Rocuronium bromide.
It does not contain all the available information.
It does not take the place of talking to your doctor.
All medicines have risks and benefits. Your doctor has weighed the risks of you having Rocuronium bromide against the benefits they expect it will have for you.
If you have any concerns about taking this medicine, ask your doctor.
Keep this leaflet.
You may need to read it again.

What Rocuronium bromide is used for

Rocuronium bromide 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 bromide 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 bromide are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. Rocuronium bromide 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 bromide is not addictive.

Before you are given Rocuronium bromide

When you must not be given it

You must not be given Rocuronium bromide 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.

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 bromide 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 bromide 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 bromide for you.
Rocuronium bromide 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.
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 bromide 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 bromide.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.
Some medicines may be affected by Rocuronium bromide or affect how well it works. These include:
• anaesthetics, medicines to make you sleep during surgery