

Rocuronium Sandoz®

rocuronium bromide solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rocuronium Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Rocuronium Sandoz is used for

Rocuronium Sandoz contains the active ingredient rocuronium bromide.

Rocuronium bromide belongs to 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.

Rocuronium Sandoz works by blocking nerve impulses which are usually sent to the muscles 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 Sandoz are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up. Rocuronium Sandoz can also be used in Intensive Care to keep your muscles relaxed.

Ask your doctor if you have any further questions about this medicine.

Rocuronium Sandoz is not addictive.

Before you are given Rocuronium Sandoz

When you must not be given it

You must not be given this medicine if you have allergies to:

- rocuronium bromide, the active ingredient
- any of the other ingredients listed at the end of this leaflet under Product description.

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.

This medicine should not be given to a child under the age of 1 month.

Safety in children younger than 1 month has not been established.

Before you are given it

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

Tell your doctor if you have or have had any of the following medical conditions:

- an allergy to muscle relaxants
- kidney disease
- liver or gallbladder disease
- heart disease
- diseases affecting nerves or muscles
- oedema (local or generalised swelling due to fluid).

Certain medical conditions may increase the effect of Rocuronium Sandoz:

- low potassium levels in the blood (e.g. after severe vomiting or diarrhoea)
- low calcium levels in the blood
- high magnesium 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.

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Rocuronium Sandoz.

Taking other medicines

Tell your doctor or pharmacist 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 Sandoz or affect how well it works. These include:

- anaesthetics, medicines to make you sleep during surgery
- corticosteroids, anti-inflammatory medicines when used concurrently with Rocuronium Sandoz in the Intensive Care Unit
- some 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 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 different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid using this medicine.

How Rocuronium Sandoz is given

Rocuronium Sandoz will be given by a doctor. It will not be given to

you until you are asleep from the anaesthetic.

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

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 (overdose)

As Rocuronium Sandoz 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. 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 medicine that reverses the effects of rocuronium bromide.

Side effects

Tell your doctor as soon as possible if you do not feel well.

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 lists 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 any of the following and they worry you:

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

Tell your doctor as soon as possible if you notice any of the following:

- fast heartbeat
- dizziness and light-headedness (low blood pressure)
- muscle weakness or paralysis
- wheezing, coughing, difficulty breathing
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, lips, tongue and throat which may cause difficulty in swallowing or breathing, shortness of breath, wheezing
- swelling of other parts of the body.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After having Rocuronium Sandoz

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 Sandoz.

Storage

Rocuronium Sandoz is stored in hospital.

It should be kept in the refrigerator at 2-8°C and not be frozen. The product 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

Rocuronium Sandoz 50mg/5mL solution for injection is a clear, colourless to yellow/orange solution. It is available in packs of 10 vials.

Ingredients

Active ingredients:

- Rocuronium Sandoz 50mg/5mL solution for injection contains 50mg of rocuronium bromide.

Inactive ingredients:

- sodium acetate trihydrate
- sodium chloride
- sodium hydroxide
- acetic acid - glacial
- water for injections.

The rubber stoppers used with Rocuronium Sandoz are latex-free.

Supplier

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