

PART III: CONSUMER INFORMATION

^{Pr} Rocuronium Bromide Injection

Rocuronium Bromide 10 mg/mL Solution for Injection

Sterile

This leaflet is part III of a three-part “Product Monograph” published when Rocuronium Bromide Injection was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Rocuronium Bromide Injection. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Rocuronium Bromide Injection is one of a group of drugs called muscle relaxants for anesthesia. These drugs are used during an operation as part of the general anesthetic. When you have an operation your muscles may have to be completely relaxed. This makes it easier for the surgeon to perform the operation.

What it does:

Rocuronium Bromide Injection blocks the nerve impulses to move your muscles. 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. At the end of surgery the effects of Rocuronium Bromide Injection are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up.

When it should not be used:

If you are hypersensitive (allergic) to rocuronium, the bromide ion or any of the other ingredients in Rocuronium Bromide Injection.

What the medicinal ingredient is:

rocuronium bromide

What the nonmedicinal ingredients are:

Glacial acetic acid, sodium acetate trihydrate, sodium chloride, sodium hydroxide, water for injections.

What dosage forms it comes in:

Rocuronium Bromide Injection 10 mg/ mL is an aqueous solution for intravenous injection only. It is supplied in 5 mL clear multidose vials, boxes of 10.

WARNING AND PRECAUTIONS

Serious Warnings and Precautions

As for all drugs used during an operation, this drug should be administered only in a facility prepared to give resuscitation and life support by adequately trained health care professionals familiar with its actions, characteristics, and hazards.

Your medical history can influence the way that Rocuronium Bromide Injection is given to you. Tell your doctor if you have now or have ever had any of the following:

- an allergy to muscle relaxants
- a decreased kidney function or kidney disease
- a heart disease or heart valve disease
- pulmonary hypertension
- oedema (fluid retention for example at the ankles)
- recent, severe vomiting, diarrhea, and “water pill” use
- a liver or gallbladder disease or decreased liver function diseases affecting nerves or muscles.

Tell your doctor if you have any other medical conditions, as they may influence how Rocuronium Bromide Injection works.

Elderly / Children

Rocuronium Bromide Injection can be used in children (from term newborns to adolescence) and elderly.

Pregnancy and Breast-Feeding

Tell your doctor if you are pregnant, or suspect that you are pregnant, or if you are breast-feeding.

Driving and Using Machines

Your doctor will inform you when it is safe to drive and operate potentially dangerous machinery after you have been administered Rocuronium Bromide Injection

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This will help your doctor to decide the correct dose of Rocuronium Bromide Injection for you.

PROPER USE OF THIS MEDICATION

Usual Dose:

The doctor will determine the dose. You will be given Rocuronium Bromide Injection before and/or during a surgical procedure. The usual dose is 0.6 mg rocuronium bromide per kg body weight and the effect lasts about 30 to 40 minutes. Your doctor may adjust the dose according to your need during the surgery.

Method and route of administration:

Rocuronium Bromide Injection is given by an adequately trained health care professional. It is not meant to be administered by yourself. Rocuronium Bromide Injection is injected in a vein as a solution. It is administered as one single injection or continuous infusion.

Only an adequately trained health care professional may give Rocuronium Bromide Injection.

Overdose:

As medical personnel will be monitoring your condition during the procedure it is unlikely that you will be given too much Rocuronium Bromide Injection. However, if this happens artificial respiration will be continued until you are able to breathe again on your own. It is possible to counteract the effects of (too much) Rocuronium Bromide Injection and speed-up your recovery by giving you a drug that reverses the effects of Rocuronium Bromide Injection.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Rocuronium Bromide Injection can have side effects, although not everybody gets them.

AFTER SURGERY

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

For the following serious side effects, you must seek immediate emergency medical treatment

- Allergic reactions (rash, swelling of the face, throat, lips, difficulty breathing).
- Feeling cold and/or clammy
- Difficulty breathing/choking/wheezing
- Muscle weakness or paralysis
- Rapid or slow heart beat
- Sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and weakness in your muscles
- Seizure/seizure-like activity

For the following serious side effects, call your doctor or pharmacist

- Dizziness especially upon standing up quickly
- High or low blood pressure if measured
- Severe itching
- Increase or decrease in blood glucose if measured
- Jaundice/yellowing of the skin/eyeballs

This is not a complete list of side effects. For any unexpected effects after receiving Rocuronium Bromide Injection, contact your doctor or pharmacist.

HOW TO STORE IT

Rocuronium Bromide Injection is handled only by qualified professionals.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adversereaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about Rocuronium Bromide Injection:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.sandoz.com, or by calling, at: 1-800-361-3062

or

by written request at:

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or by e-mail at :

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