

PART III: CONSUMER INFORMATION**^{Pr}Rocuronium Bromide Injection**

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 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 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:

Sodium acetate anhydrous, sodium chloride, water for injections. May contain sodium hydroxide, and/or glacial acetic acid to adjust the pH to approximately 4.0. No preservative has been added.

What dosage forms it comes in:

Rocuronium Bromide Injection is a colorless to slightly yellow/brown solution containing 10 mg/mL rocuronium bromide, which is administered intravenously either as a bolus injection or as a continuous infusion. It is available in vials containing 50 mg (10 vials per pack).

WARNINGS 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 adolescents) 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.

If you think you have taken too much ROCURONIUM BROMIDE INJECTION, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

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/whooping
- 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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions 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/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); or by contacting the sponsor, Pfizer Canada ULC at: 1-800-463-6001.

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Last revised: May 31, 2019