PART III: CONSUMER INFORMATION

ZEMURON®
Rocuronium Bromide

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

ABOUT THIS MEDICATION

What the medication is used for:
ZEMURON® 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:
ZEMURON® 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 ZEMURON® 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 ZEMURON®.

What the medicinal ingredient is:
rocuronium bromide

What the nonmedicinal ingredients are:
Acetic acid, nitrogen, sodium acetate, sodium chloride, water for injections.
Each milliliter (mL) ZEMURON® contains 1.72 mg sodium. No preservative has been added.

What dosage forms it comes in:
ZEMURON® is a colorless to slightly yellow/brown solution for injection or infusion containing 10 mg/mL rocuronium bromide. It is available in vials containing 50 mg (10 vials per pack) and 100 mg rocuronium bromide (10 vials per pack).
Not all pack sizes may be marketed.

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 ZEMURON® 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 ZEMURON® works.

Elderly / Children
ZEMURON® 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 ZEMURON®.

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 ZEMURON® for you.

PROPER USE OF THIS MEDICATION

Usual Dose:
The doctor will determine the dose. You will be given ZEMURON® 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:
ZEMURON® is given by an adequately trained health care professional. It is not meant to be administered by yourself. ZEMURON® 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 ZEMURON®.

Overdose:
As medical personnel will be monitoring your condition during the procedure it is unlikely that you will be given too much ZEMURON®. 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) ZEMURON® and speed-up your recovery by giving you a drug that reverses the effects of ZEMURON®.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ZEMURON® 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 ZEMURON®, *contact your doctor or pharmacist.*

HOW TO STORE IT

ZEMURON® 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 the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 1908C
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

or at Merck Canada Inc. by one of the following 2 ways:
• Call toll-free at 1-800-567-2594
• Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-800-369-3090, or
  - Mail to: Merck Canada Inc.
    Pharmacovigilance
    16750 route Transcanadienne
    Kirkland, QC H9H 4M7

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

This document plus the full product monograph, prepared for health professionals can be found at www.merck.ca or by contacting the sponsor, Merck Canada Inc. at: 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

Last Revised: November 5, 2018