

## PART III: CONSUMER INFORMATION

### Pr NIMBEX<sup>®</sup> cisatracurium besylate injection

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

- NIMBEX<sup>®</sup> is used for providing muscle relaxation during surgery, or during other medical procedures. NIMBEX<sup>®</sup> is only used in conjunction with an anesthetic.

##### What it does:

NIMBEX<sup>®</sup> belongs to a group of medicines called neuromuscular blockers. It works by blocking the effects of acetylcholine, a chemical involved in muscle contraction. This relaxes muscles in the body before surgery or insertion of a breathing tube.

##### When it should not be used:

Nimbex should not be used in neonates (infants less than 1 month of age) or low birth weight infants. Before surgery, be sure to tell all consulting physicians if you:

- are allergic to cisatracurium besylate;
- are allergic to any other bis-benzylisoquinolinium agents;
- are allergic to benzyl alcohol.

##### What the medicinal ingredient is:

cisatracurium besylate

##### What the non-medicinal ingredients are:

NIMBEX<sup>®</sup> also contains benzenesulfonic acid, benzyl alcohol and water for injection.

##### What dosage forms it comes in:

NIMBEX<sup>®</sup> is available as an injection in vials of 2 mg/mL (10 mL multiple-dose vial).

#### WARNINGS AND PRECAUTIONS

**BEFORE you use NIMBEX<sup>®</sup> talk to your doctor or pharmacist if:**

- You have difficulty with intubations
- You are susceptible to malignant hyperthermia

- You have kidney or liver problems
- You are pregnant, plan to become pregnant, or are breast-feeding
- You are taking any prescription or non-prescription medications or herbal medicines
- You are allergic to cisatracurium besylate, other medications or substances (e.g., benzyl alcohol)
- You have muscle weakness or partial paralysis on one side of the body or partial paralysis affecting the lower limbs (e.g., Lambert-Eaton syndrome, myasthenia gravis)
- You have an electrolyte disturbance or acid-base imbalance or tissue wasting, or are debilitated
- You have had a burn injury requiring medical treatment

NIMBEX<sup>®</sup> contains benzyl alcohol, which could be lethal to neonates (infants less than 1 month of age) and low birth weight infants.

#### INTERACTIONS WITH THIS MEDICATION

**Drugs that may interact with NIMBEX<sup>®</sup> include:**

- succinylcholine
- inhalation anesthetics (e.g., isoflurane, enflurane)
- anticonvulsants (e.g., phenytoin, carbamazepine)
- antibiotics (e.g., aminoglycosides, tetracyclines, bacitracin, polymyxins, lincomycin)
- anti-arrhythmics (e.g., procainamide and quinidine)
- lithium and magnesium salts
- local anesthetics

#### PROPER USE OF THIS MEDICATION

##### Usual dose:

NIMBEX<sup>®</sup> is a medicine that is given by injection. NIMBEX<sup>®</sup> will be administered by an anesthetist or other trained professional during surgery or other medical procedures. The dosage will vary according to many factors such as body weight, age and the duration of the procedure. It will be given to you once you are anesthetised (lost all awareness) for your surgery or procedure.

##### Overdose:

- Overdoses of NIMBEX<sup>®</sup> lead to prolonged relaxation of the body's muscles. This can be readily treated; however, this situation is unlikely to occur because NIMBEX<sup>®</sup> is only administered by an anesthetist or other trained doctor who will closely monitor your progress.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, NIMBEX® can cause uncommon side effects which include flushing, skin rashes, feeling agitated, increased cough, nausea, and vomiting.

After exposure to NIMBEX®, you should contact your physician or anesthesia professional if you have any of the side effects listed in the table below.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom/effect	Talk with your doctor or anesthesia professional		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common	Allergic Reactions		✓
	- Rash		✓
	- Hives		✓
	- Swelling of the face, throat, lips		✓
	- Difficulty breathing		✓
	-Difficulty swallowing		✓
	Chills		✓
	Difficulty Breathing/ Choking		✓
	Dizziness		✓
	Elevated Blood Glucose		✓
	High Blood Pressure		✓
	Jaundice/Yellowing of the Eyeballs		✓
	Low Blood Pressure		✓
	Rapid Heartbeat		✓
	Seizures/Seizure-like activity		✓
	Severe Itching		✓
	Slow Heartbeat		✓
	Sudden fever with stiffness, pain and weakness in muscles		✓
	Wheezing		✓

*This is not a complete list of side effects. For any unexpected effects while taking NIMBEX®, contact your doctor or pharmacist.*

**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 on line at:  
[www.healthcanada.gc.ca/medeffect](http://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
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

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

*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:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at: 1-800-699-9948

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