

## PART III: CONSUMER INFORMATION

### <sup>Pr</sup> ISOFLURANE volatile liquid isoflurane

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

### ABOUT THIS MEDICATION

#### What the medication is used for:

ISOFLURANE is used as a general anesthetic during surgery.

#### What it does:

ISOFLURANE causes unconsciousness, muscle relaxation, and loss of sensation over the entire body so that surgery can be performed.

#### When it should not be used:

ISOFLURANE should not be used in patients who:

- are allergic to isoflurane or other halogenated agents
- have a history of liver inflammation (hepatitis) due to the use of an inhaled general anesthetic, or have experienced liver problems, jaundice, unexplained fever, or certain types of inflammation reactions after a previous halogenated anesthetic administration.
- have been told by their doctors that they are genetically susceptible to a dangerously high body temperature when given some drugs used for general anesthesia (malignant hyperthermia MH).

#### What the medicinal ingredient is:

isoflurane

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

The finished product is composed only of the active ingredient, isoflurane.

#### What dosage forms it comes in:

ISOFLURANE is available as a 99.9% pure volatile liquid in 100 mL and 250 mL amber coloured bottles.

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

- ISOFLURANE should only be administered by qualified individuals trained in general anesthesia in an adequately equipped facility.
- ISOFLURANE may trigger a rise in blood potassium or body temperature. You may experience stiff muscles, changes in blood pressure, rapid breathing, a bluish colour to lips or fingers, rapid or irregular heart rate. Trained healthcare professionals will take care of you if this happens.

#### **BEFORE you undergo general anesthesia, tell your anesthesia professional if:**

- You have kidney or liver problems.
- You are pregnant or nursing.
- You are allergic to isoflurane.
- You are susceptible to malignant hyperthermia (MH) .
- A doctor has difficulty placing a tube down your throat to help you breathe.
- You are suffering from any other illness, such as diabetes, severe headaches, cancer, problems with your nerves or muscles (especially muscular dystrophy), nausea or vomiting.
- You have or are at risk for developing Increased Intracranial Pressure (ICP). ICP is increased pressure inside the skull with general symptoms such as headache, vomiting without nausea, altered level of consciousness, back pain, and changes to your eyesight.
- You have low blood pressure, heart, kidney or liver problems.
- You are taking prescription or non-prescription medications or herbal medicines.
- You have a mitochondrial disorder, which is a disorder that people may be born with and may affect special cells of the heart, brain, and kidney.

Performance of activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, may be impaired for up to six days after general anesthesia. Wait 6 days and use caution before resuming these activities.

As with other anesthetics, small changes in moods may persist for several days following administration.

**INTERACTIONS WITH THIS MEDICATION**

**Serious Drug Interactions**

- Tell your healthcare professional if you have muscular diseases (especially muscular dystrophy) and:
  - you are taking potassium and/or
  - you have heart problems, especially irregular heartbeats

**Drugs that may interact with ISOFLURANE include:**

- Benzodiazepines (Valium<sup>®</sup>, midazolam)
- Calcium antagonists (drugs used for the treatment of conditions such as high blood pressure, angina, abnormal heart rhythms)
- Isoniazid
- Neuromuscular blocking agents
- Nitrous oxide
- Nondepolarizing relaxants
- Non-selective MAO-inhibitors (used for the treatment of depression)
- Opioids (morphine, codeine)
- Other sedative agents
- Sympathomimetic agents (adrenaline, noradrenaline)

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

The proper dose is determined by a doctor trained in the administration of general anesthesia.

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

Common side effects of ISOFLURANE include shivering, nausea, and vomiting.

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

After exposure to ISOFLURANE, you should contact your doctor or anesthesia provider if you have any of the following reactions:

<b>Common</b>	Agitation, confusion
	Chills/shivering
	Difficulty breathing
	Increased blood sugar: frequent urination, thirst, hunger
	Liver disorders: yellow colour to skin and eyes, dark urine
	Muscle pain
	Nausea, vomiting
	Nervous system disorders: confusion, nervousness, abnormal gait, dizziness, drowsiness, intellectual function decreased
	Rash
	Slow, rapid or irregular heartbeat
<b>Uncommon</b>	Weakness
	High blood pressure: headache, altered vision, nausea, vomiting
	Low blood pressure: light-headedness, fainting, especially when getting up from a lying or sitting position
	Malignant hyperthermia: sudden fever with stiffness, pain and weakness in your muscles
<b>Frequency Unknown</b>	Seizure or fits
	Heart attack: chest pain shortness of breath, heartburn, sweating, weakness, fatigue, light-headedness, nausea

***This is not a complete list of side effects. For any unexpected effects while taking ISOFLURANE, contact your doctor, anesthesia professional 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 0701D  
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**

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals can be found at:

[www.abbvie.ca](http://www.abbvie.ca)

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, Qc H4S 1Z1 at:  
1-888-704-8271

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