

PART III: CONSUMER INFORMATION

Pr ISOFLURANE® (isoflurane)

This leaflet is part III of a three-part "Product Monograph" published when 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 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 nonmedicinal ingredients are:

The finished product is composed solely 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

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 taking prescription or non-prescription

medications or herbal medicines.

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

Drugs that may interact with ISOFLURANE® include the:

Benzodiazepines (Valium, Versed)
Opioids (Morphine, Codeine)

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 include: shivering, nausea, and vomiting.

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

After exposure to ISOFLURANE®, you should immediately contact your physician or anesthesia professional if you have any of the following reactions:

Symptoms of malignant hyperthermia: sudden fever with stiffness, pain and weakness in your muscles

Symptoms of low blood pressure: dizziness/fainting

Difficulty breathing

Irregular heartbeats

A lack of passage of material through the bowel, with signs of abdominal pain, vomiting, shivering, nausea and constipation
Sudden confusion or lack of ability to pay attention and/or focus

Hallucinations

Hiccups

Jaundice (yellowing of the skin and/or eyeballs)

Symptoms of elevated rise in blood sugar: confusion, increased hunger and/or thirst, increased frequency of urination, fruity breath.

Isolated cases of seizures [(i.e., loss of consciousness with uncontrollable shaking ("fit"))].

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

HOW TO STORE IT

ISOFLURANE[®] should be stored between 15°C and 25°C.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax: 866-678-6789

On-line: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office

Marketed Health Products Safety and

Effectiveness Information Division

Marketed Health Products Directorate

Health Products and Food Branch

Health Canada

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Canada Vigilance, you should contact your physician or pharmacist.

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, at: 1-800-699-9948.

This leaflet was prepared by Abbott Laboratories, Limited

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