

PART III: CONSUMER INFORMATION

^{Pr}SEVORANE[®] AF volatile liquid sevoflurane

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

ABOUT THIS MEDICATION

What the medication is used for:

SEVORANE[®] AF is an inhalation general anesthetic used during surgery.

What it does:

SEVORANE[®] AF causes unconsciousness, muscle relaxation, and loss of sensation over the entire body so that surgery can be performed.

When it should not be used:

SEVORANE[®] AF should not be used in patients who:

- are allergic to SEVORANE[®] AF or other halogenated agents
- have experienced liver problems, jaundice, unexplained fever, or certain types of inflammation reactions after a previous halogenated anesthetic administration
- are susceptible to malignant hyperthermia

What the medicinal ingredient is:

sevoflurane

What the non-medicinal ingredients are:

The finished product is composed solely of the active ingredient, sevoflurane.

What dosage forms it comes in:

SEVORANE[®] AF is available as a volatile liquid that is 99.9875% pure.

WARNINGS AND PRECAUTIONS

Recovery of consciousness following SEVORANE[®] AF administration generally occurs within minutes. As with other anesthetics, small changes in moods may persist for several days following administration.

Performance of activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, may be impaired for some time after general anesthesia.

INTERACTIONS WITH THIS MEDICATION

Many drugs may interact with SEVORANE[®] AF. Tell your doctor if you had a history of drug interactions. Your doctor will manage according to your condition.

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

Known side effects when you wake up include: feeling agitated, increased cough, nausea, and vomiting.

You should talk to your anesthesia professional prior to surgery if you are aware of any of the following conditions:

- you have difficulty with airway intubations
- you are susceptible to malignant hyperthermia
- you are taking medications, nonprescription medications, or herbal medicines
- you have kidney or liver problems
- you have Pompe's disease or a mitochondrial disorder
- you are pregnant or nursing

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

After your surgery you should tell your doctor if you have any of the following reactions:

- chills
- difficulty breathing/choking
- dizziness
- elevated rise in blood glucose, if measured
- high blood pressure
- hives
- jaundice/yellowing of the eyeballs
- low blood pressure, if measured
- mild to severe allergic reactions
- rapid heartbeat
- rash
- seizures/seizure-like activity
- severe itching
- slow heartbeat
- sudden fever with stiffness, pain and weakness in your muscles
- wheezing

This is not a complete list of side effects. For any unexpected effects while taking SEVORANE® AF, 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
- **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

This leaflet was prepared by Abbott Laboratories, Limited.

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