

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

<sup>Pr</sup>SEVORANE<sup>®</sup> AF

sevoflurane volatile liquid

Read this carefully before the administration of **SEVORANE AF**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SEVORANE AF**.

#### Serious Warnings and Precautions

- SEVORANE AF should only be administered by a healthcare professional trained in using general anesthesia.
- SEVORANE AF must only be used in a medical setting where you can be properly monitored and cared for.

#### What is SEVORANE AF used for?

- SEVORANE AF is used in adults and children to put them to sleep during surgery (general anesthesia).

#### How does SEVORANE AF work?

SEVORANE AF contains the medicinal ingredient sevoflurane which belongs to a group of medicines called general anesthetics. Sevoflurane is a liquid, that when put into a special machine becomes a gas. This gas mixes with the oxygen you will be breathing in during surgery. SEVORANE AF works by temporarily reducing the activity of the body's central nervous system. This causes a loss of consciousness, muscle relaxation and loss of sensation. This allows surgery to be carried out without pain or distress.

#### What are the ingredients in SEVORANE AF?

Medicinal ingredient: sevoflurane

Non-medicinal ingredient: none

#### SEVORANE AF comes in the following dosage forms:

volatile liquid: 99.9875% v/v

**Do not use SEVORANE AF if you:**

- are allergic to sevoflurane or any other general anesthetic medicines.
- have had liver problems, jaundice (yellowing of the skin or eyes), unexplained fever, or certain types of inflammation reactions after having a general anesthetic.
- or a family member have had malignant hyperthermia (a serious, sometimes deadly, reaction to anesthesia where your body temperature becomes dangerously high and your muscles contract).
- have been told that you should not receive general anesthesia.

**To help avoid side effects and ensure proper use, talk to your anesthesia professional prior to surgery. Talk about any health conditions or problems you may have, including if you:**

- have difficulty with airway intubations (having a tube put down your throat to help you breathe).
- have kidney or liver problems.
- have heart problems.
- have a neuromuscular disease such as Duchenne muscular dystrophy.
- have a history of seizures or fits.
- have a mitochondrial disorder.
- are pregnant.
- are breastfeeding. You should not breastfeed for 48 hours after receiving SEVORANE AF.

**Other warnings you should know about:**

Once you have stopped receiving SEVORANE AF you should regain consciousness within minutes. Like with other anesthetics, you might notice small changes in your mood. This might last for several days after you have had SEVORANE AF. Talk to your healthcare professional if this becomes severe.

**Pompe's disease and Down syndrome:** If your child has Pompe's disease or Down syndrome it is important to let their healthcare professional know before they are given SEVORANE AF.

**Driving and using machines:** Give yourself time after being given SEVORANE AF to see how you feel before driving a vehicle or using machinery. It might take some time for you to become fully alert.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with SEVORANE AF:**

- alcohol
- benzodiazepines (a type of sedative)
- calcium antagonists (high blood pressure and heart medicine)
- isoniazid (an antibiotic used to treat tuberculosis)
- non-selective MAO-inhibitors (a type of antidepressant)
- opioids (pain medicine)

Tell your healthcare professional if you have a history of drug interactions. Your healthcare professional will manage this according to your condition.

**How to take SEVORANE AF:**

SEVORANE AF will always be given to you by a healthcare professional trained in the administration of general anesthesia.

**Usual dose:**

Your healthcare professional will decide on the dose that is right for you.

**Overdose:**

If you think you, or a person you are caring for, have been given too much SEVORANE AF, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using SEVORANE AF?**

These are not all the possible side effects you or your child may have after being given SEVORANE AF. If you or your child experience any side effects not listed here, tell your healthcare professional.

Side effects when you wake up may include:

- feeling agitated
- increased cough
- nausea
- vomiting
- chills
- dizziness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Low blood pressure:</b> dizziness, fainting, lightheadedness (may occur when you go from lying or sitting to standing up)		√	
<b>COMMON</b>			
<b>Heart rate problems:</b> change in heartbeat (slow or fast)		√	
<b>High blood pressure:</b> headaches, dizziness,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
shortness of breath			
<b>UNCOMMON</b>			
<b>Breathing problems:</b> difficulty breathing/choking, wheezing		√	
<b>High blood sugar:</b> frequent urination, thirst, and hunger		√	
<b>UNKNOWN</b>			
<b>Allergic reaction:</b> rash, itching, hives, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing			√
<b>Liver problems:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
<b>Malignant hyperthermia:</b> sudden fever, stiffness, pain and weakness in the muscles			√
<b>Seizures or fits</b>			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

SEVORANE AF will be stored by your healthcare professional.

### If you want more information about SEVORANE AF:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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