

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

Pr ISOFLURANE
(isoflurane, USP)

Read this carefully before you start taking ISOFLURANE (isoflurane) and each time you get a refill. This leaflet is a summary and will not tell you everything about ISOFLURANE. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ISOFLURANE.

ABOUT THIS MEDICATION

What the medication is used for:

ISOFLURANE (isoflurane) is used to put you under general anesthesia.

What it does:

ISOFLURANE (isoflurane) is used to induce and maintain anesthesia.

When it should not be used:

ISOFLURANE should not be used if:

- You have been told that you are allergic to isoflurane or other inhaled general anesthetics, or components of the container.
- You have a history of liver inflammation (hepatitis) due to the use of an inhaled general anesthetic or have experienced unexplained liver problems (for example jaundice with fever) after a previous use of an inhaled general anesthetic.
- You or any member of your family has experienced a condition called malignant hyperthermia (a genetic disorder that causes rapid raise in body temperature) during an operation.

What the medicinal ingredient is:

Isoflurane, USP

What the nonmedicinal ingredients are:

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

What dosage forms it comes in:

ISOFLURANE (isoflurane) is available as liquid (100% v/v) supplied in 100 mL amber-colored bottles. The liquid is changed to gas in a vaporizer for inhalation. The vaporizer is designed to be used only with ISOFLURANE.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- ISOFLURANE (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 health care professionals will take care of you if this happens.

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

- You have been told that you are allergic to isoflurane or other inhaled general anesthetics, or components of the container.
- You have previously had general anesthesia, particularly if repeated over a short period of time.
- A doctor has difficulty placing a tube down your throat to help you breathe.
- You are pregnant (or may be pregnant).
- You are breast-feeding.
- You or a member of your family suffers from malignant hyperthermia (a genetic disorder that causes rapid raise in body temperature).
- 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.

Recovery of consciousness following ISOFLURANE (isoflurane) administration generally occurs within minutes. Change in mood may persist for several days following administration.

Performance of activities requiring mental alertness or coordination such as operating a motor vehicle or hazardous machinery may be impaired for some time after general anesthesia. Do not drive a motor vehicle or operate hazardous machinery for at least 24 hours after having a general anesthetic.

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 heart beats

Tell your doctor, nurse or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Drugs that may interact with ISOFLURANE (isoflurane) include:

- Other anesthetics, tranquilizers (e.g., benzodiazepines), narcotics (e.g., opioids), muscle relaxants (e.g. pancuronium), and nitrous oxide gas.
- Calcium channel blockers (e.g., used to treat high blood pressure or seizures)
- Beta blockers (e.g., used to treat high blood pressure and heart problems)
- Monoamine Oxidase (MAO) inhibitors (e.g., used to treat depression, anxiety and migraine)
- Isoniazid (a treatment for tuberculosis)
- Indirect-acting sympathomimetics (amphetamines and their derivatives, psychostimulants, appetite suppressants, ephedrine and its derivatives)
- Alcohol (chronic use before anesthesia)
- St. John’s Wort

PROPER USE OF THIS MEDICATION

Usual Dose:

Your anesthesia provider will decide what dose of ISOFLURANE (isoflurane) you will receive. The dose will vary depending on your age, weight, the type of anesthesia that you are having, and other factors.

Overdose:

Overdosage will be handled by the anesthesia provider.

In case of drug overdose (especially if you have accidentally come in contact with ISOFLURANE (isoflurane) on your skin, in your eyes, by swallowing it or by breathing it in), contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects include headache, cough, fatigue, mood changes, and nightmare.

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

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

Common	Agitation, Confusion
	Chills/Shivering
	Difficulty Breathing
	Increased Blood Sugar: frequent urination, thirst, and hunger
	Liver Disorders: yellow color 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
Uncommon	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
Frequency Unknown	Seizure or Fits
	Heart Attack: chest pain, shortness of breath, heart burn, sweating, weakness, fatigue, light-headedness, nausea

This is not a complete list of side effects. For any unexpected effects while taking ISOFLURANE (isoflurane), contact your doctor, anesthesia provider, or pharmacist.

HOW TO STORE IT

ISOFLURANE (isoflurane) should only be administered in an adequately equipped facility. ISOFLURANE must be kept out of reach and sight of children. **It is stored at room temperature (15° to 30°C).**

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/adverse-reaction-reporting.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.

MORE INFORMATION

If you want more information about ISOFLURANE (isoflurane):

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by contacting Blue-Zone Technologies Ltd. (www.blue-zone.ca), or by calling 1-844-761-1224.

This leaflet was prepared by Blue-Zone Technologies Ltd., Concord, Ontario, L4K 3C1.

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