

Piramal Sevoflurane™

Liquid for inhalation, anaesthetic 100% v/v bottle
SEVOFLURANE

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Piramal Sevoflurane™.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Piramal Sevoflurane™ against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Piramal Sevoflurane™ is used for?

Piramal Sevoflurane™ belongs to a group of medicines called halogenated anaesthetic agents, which are breathed in to induce and/or maintain anaesthesia.

This medicine is administered by an anaesthetist in the air you breathe when you go for surgery. It is a colourless liquid supplied in a glass bottle. It is given by your anaesthetist using a vaporiser, which turns the liquid into a gas so that you can breathe it in.

Piramal Sevoflurane™ is used for inducing and maintaining heavy sleep needed during surgery. The medicine produces loss of consciousness and pain sensations during surgery.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you receive Piramal Sevoflurane™

Before you are due to receive Piramal Sevoflurane™

You must tell your doctor if:

- You have previously had any problems with a general anaesthetic.**
- You or anyone in your family has malignant hyperthermia (a rare type of severe fever).**
- You have recently had any other general anaesthetic, or had more than one general anaesthetic over a short period of time**
- You have had Piramal Sevoflurane™ before and experienced an allergic reaction.**
- You have or have had the following medical conditions:**
 - Any problems with your liver including hepatitis
 - Growths or abnormalities in your brain
 - Heart disease; for example coronary artery disease, high or low blood pressure
 - Lung problems, for example asthma
 - Any problems with your kidneys
 - Any problems with your nerves and muscles (neuromuscular disease)
 - Mitochondrial disorders
 - Pompe's disease

- You are on the following medications:**
Muscle relaxants

These medicines may affect the way your doctor gives you Piramal Sevoflurane™.

Tell your doctor also if you are taking any other medicines that you buy without a prescription from your pharmacy, supermarket or health food shop

- You are pregnant or suspect you may be pregnant.**

The safety of Piramal Sevoflurane™ during pregnancy is not yet known.

- You are breast-feeding.**

It is not known whether sevoflurane passes into breast milk. Your doctor will advise you on what to do if you are breastfeeding.

When you must not receive Piramal Sevoflurane™

Piramal Sevoflurane™ should not be given to patients who are not suitable for receiving a general anaesthetic.

Piramal Sevoflurane™ should not be given to patients who are allergic or sensitive to halogenated anaesthetic agents.

Before Piramal Sevoflurane™ is started

Piramal Sevoflurane™ may cause drowsiness, tiredness or weakness for a while after it has been administered. It may also cause problems with coordination and ability to think.

Therefore, for at least 24 hours Piramal Sevoflurane™ (or longer if necessary) after receiving Piramal Sevoflurane™, do not drive, operate moving machinery, or do anything else that could be dangerous if you are not alert.

Ask your doctor when you can drive and/or return to work involving machinery or heavy equipment.

Unless otherwise directed by your doctor, do not drink alcoholic beverages or take other central nervous system (CNS) depressants (medicines that may make you drowsy or less alert) for about 24 hours after you have received Piramal Sevoflurane™. Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies or colds; other sedatives, tranquillisers or sleeping medicine, prescription pain medicine or narcotics; barbiturates; medicines for seizures; and muscle relaxants.

How Piramal Sevoflurane™ is given

Only persons trained in the administration of general anaesthesia give Piramal Sevoflurane™. It is given using a vaporiser. The dose of Piramal Sevoflurane™ will be adjusted to keep you at the right depth of sleep.

If you are given too much Piramal Sevoflurane™

As Piramal Sevoflurane™ is given under strict supervision it is unlikely that you will

receive too much. However, the anaesthetist can reduce the dose of Piramal Sevoflurane™ and provide oxygen should your blood pressure be too low or you have difficulty in breathing.

Side effects

As with all medicines, unwanted effects sometimes happen. Rarely Piramal Sevoflurane™ may produce unwanted effect, which you may wish to know about.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Piramal Sevoflurane™ may cause some lowering of blood pressure and breathing rate, changes in heart rate or seizures. You will not know about these things since you will be asleep but your anaesthetist will adjust the dose of Piramal Sevoflurane™ as necessary and will give you other medicines if needed.

Piramal Sevoflurane™ may cause coughing, dizziness, drowsiness and increased salivation.

Piramal Sevoflurane™ may cause disturbances of liver function in some people. After your operation, tell your doctor if you develop the following symptoms of liver problems: nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions and/or dark coloured urine.

Some people may experience shivering, nausea and vomiting upon waking from the general anaesthesia.

It is possible that Piramal Sevoflurane™ may cause a rare group of symptoms known as malignant hyperthermia. The features of this are muscle rigidity, fast pulse, breathing heavily and quickly, bluish lips and skin, changes in blood pressure and a fever. Your doctor will treat this by stopping the Piramal Sevoflurane™ and using other medications as needed.

After anaesthesia there may be a brief rise in your white blood cell count. Your doctor will monitor this if it happens.

Product description

What it looks like

Piramal Sevoflurane™ is a colourless liquid supplied in an amber bottle.

Ingredients

Each bottle contains 250mL of the active substance sevoflurane.

Manufacturer

Piramal Sevoflurane™ is manufactured by Piramal Critical Care Inc., 3950 Schelden Circle, Bethlehem, Pennsylvania 18017 United States of America

and distributed in Australia by:

Device Technologies Australia Pty Ltd
I Garigal Road,
Belrose, NSW 2085
(ABN 40 058 091 973)

Australian Registration Number:

Piramal Sevoflurane™ 250mL bottle AUST
R 202776

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