

Package leaflet: Information for the user

Sevoflurane 100% Inhalation Vapour, Liquid

Sevoflurane

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, surgeon or anaesthetist.
- If you get any side effects, talk to your doctor or anaesthetist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sevoflurane is and what it is used for
2. What you need to know before receiving Sevoflurane
3. How Sevoflurane is given
4. Possible side effects
5. How to store Sevoflurane
6. Contents of the pack and other information

1. What Sevoflurane is and what it is used for

Sevoflurane contains the active ingredient sevoflurane. Sevoflurane belongs to a group of medicines called anaesthetics.

Sevoflurane is an anaesthetic that is breathed in (inhaled), and is used to induce and maintain a deep, pain-free sleep (general anaesthesia) in adults and children during an operation. If Sevoflurane is used in dental operations these must be performed in a hospital or day care unit.

2. What you need to know before receiving Sevoflurane

Do not receive Sevoflurane:

- If you have been told previously that you should not receive general anaesthesia.
- If you know that you are **allergic** to sevoflurane or any other anaesthetics, or any of the other ingredients in Sevoflurane.
- If you or any member of your family has experienced a condition called malignant hyperthermia (rapid rise in body temperature) during an operation with Sevoflurane or any other anaesthetic.
- If you are undergoing dental procedures outside a hospital or day care unit.

Warnings and precautions

Talk to your doctor or anaesthetist before receiving Sevoflurane if:

- you have any other illness not connected to your operation, such as kidney, brain or heart problems, severe headaches, feeling sick or being sick.
- you have liver problems. Some anaesthetics can occasionally cause problems in the liver, which can cause yellowing of the skin and eyes (jaundice). It is important that you tell your doctor or anaesthetist if you received Sevoflurane or any other anaesthetic within the last three months.
- you have a personal or family history of QT prolongation (a disorder of the heart's electrical system that can cause irregular heartbeats and changes in your heart electrocardiogram) or torsade de pointes (a special kind of irregular heart beat).
- you are prone to or at risk of seizures (fits).
- you have a mitochondrial disorder (e.g. Leigh's syndrome), which is a disorder that people may be born with and may affect special cells of the heart, brain and kidney.
- you have low blood pressure or low blood volume or have blood circulation problems, for example due to other medication you are currently taking.

- you have coronary artery disease (narrowing of the blood vessels that supply oxygen and blood to the heart).
- you are at risk of increased intracranial pressure (rise in pressure inside the skull).
- you have respiratory depression (breathing difficulties) or have taken medicines that cause respiratory depression.
- you are undergoing an obstetrical operation.

If any of these apply to you, consult your doctor or anaesthetist before being given Sevoflurane.

In addition to the above, if Sevoflurane is to be administered to your child, please tell their ward doctor, surgeon or anaesthetist if they:

- have seizures or seizure disorders (fits), as Sevoflurane may increase the risk of seizures.
- have Pompe's disease (a metabolic disorder). Sevoflurane may produce abnormal heart rhythms, which may be severe in some cases.
- have a severe muscle disorder such as Duchenne muscular dystrophy.

Other medicines and Sevoflurane

Please tell your doctor or anaesthetist if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking;

- pain killers called opioid analgesics (e.g. alfentanil and sufentanil).
- muscle relaxants, such as succinylcholine and non-depolarising muscle relaxants.
- amphetamines (stimulants)
- beta blockers or a drug called verapamil (used to treat high blood pressure and certain heart conditions)
- isoniazid (an antibiotic used to treat tuberculosis)
- St John's Wort (a herbal remedy)
- decongestants (ephedrine)
- benzodiazepines (used to treat anxiety, sleep disorders or used as a muscle relaxant)
- barbiturates (sedative)
- nitrous oxide (anaesthetic)
- adrenaline (used to reverse severe allergic reaction)
- calcium antagonists, especially dihydropyridine (used to treat high blood pressure)
- non-selective monoamine oxidase inhibitors (used to treat depression). Treatment should be stopped two weeks prior to surgery
- medicines used to treat heart arrest (a condition where the heart stops beating) and low blood pressure such as isoprenaline, adrenaline and noradrenaline.

Sevoflurane with alcohol

Alcohol should be avoided when taking Sevoflurane.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant, or are breast-feeding, consult your doctor before receiving Sevoflurane as the safety of sevoflurane in pregnancy or breast-feeding is not known. Breast-feeding should be avoided for 48 hours after administration of Sevoflurane and breast milk discarded during that period.

Driving and using machinery

Sevoflurane may affect your ability to drive or use machines for some time after administration. Therefore, you should **NOT** drive or operate machinery until your doctor advises that you may do so.

3. How Sevoflurane is given

Sevoflurane will be given to you by an anaesthetist. Sevoflurane liquid is changed to gas in a vaporiser, and you will then breathe this in.

Very occasionally patients may be asked to breathe in the Sevoflurane gas via a mask but usually they will receive an injection of another anaesthetic to make them go to sleep before they receive Sevoflurane. Sevoflurane has a pleasant smell and you will go to sleep very rapidly and smoothly.

The dose of Sevoflurane that you receive will be decided by your anaesthetist and will vary depending on your age, weight and the type of operation that you are having.

After you have been given Sevoflurane, you will come round or wake up within a few minutes. However, you should be aware that your ability to do certain things which need full mental alertness, such as driving a car or operating dangerous machinery may be lower than usual for some time after general anaesthesia.

If you are given more Sevoflurane than you should have been given

As Sevoflurane is given to you by an anaesthetist, an overdose is unlikely but if this were to occur, you anaesthetist or doctor will manage and treat you at the time.

4. Possible side effects

As with all anaesthetics, Sevoflurane can cause side effects, although not everybody gets them. These can occur both **during** and **after** your operation. Any side effects which may occur during your operation will be managed by your doctor, as necessary.

The frequency of side effects is classified as follows;

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 10,000 people

Very common side effects of Sevoflurane include;

- restlessness
- slow heart rate
- low blood pressure
- coughing
- feeling sick (nausea) and being sick (vomiting)
- delirium

Common side effects of Sevoflurane include;

- drowsiness
- dizziness
- headache
- fast heart rate
- increased blood pressure
- shallow breathing
- throat spasm
- watering mouth
- chills
- fever
- abnormal blood sugar (glucose) level
- abnormal liver function test or white blood cell count (If you have a blood test, you may be told that you have raised liver enzymes, or raised levels of white blood cells (White blood cells are the part of the blood that fight infections). These will not normally cause any symptoms.)
- fluoride level increased (Levels of fluoride in the blood may be raised slightly during and immediately after anaesthesia, due to the body breaking down Sevoflurane, but these levels are not believed to be harmful and soon return to normal.)
- abnormally low body temperature

Uncommon side effects of Sevoflurane include;

- heart disorders (AV block), which will be closely monitored by your anaesthetist during your operation and may be recognised by dizziness after your operation

The following side effects have also been reported with unknown frequency, which may or may not be due to Sevoflurane;

- moderate and severe allergic reactions which may include; tightening/narrowing of the airway, shortness of breath, wheezing, rash, contact dermatitis, swelling face, chest discomfort. These reactions may be associated with hypersensitivity, particularly in association with long-term occupational exposure to inhaled anaesthetic agents,
- Hives,
- convulsions, particularly in children,
- twitching and jerking,
- itching of the skin,
- sudden stopping of heartbeat (cardiac arrest). There have been very rare reports of cardiac arrest associated with the use of sevoflurane,
- QT prolongation associated with Torsade,
- narrowing of the lung airways (bronchospasm),
- liver injury and liver problems including fatal liver failure in rare cases. People with liver disease may have abdominal pain or fullness, dark urine, pale or white-coloured stool, fatigue, general itching, yellowing of the eyes, nausea and vomiting,
- rapid rise in body temperature (malignant hyperthermia). Some of these reports have been fatal,
- skin rashes.

As with other anaesthetics, abnormalities of the heart rhythm (arrhythmias) can occur during anaesthesia.

Isolated reports of abnormalities in heart rhythm have been reported in children with Pompe's disease.

Other side effects which may occur while you are under anaesthetic will be managed by your anaesthetist, as necessary.

You will come round or wake up within a few minutes. Children in particular, may be restless on awakening. Tell your doctor or anaesthetist if you need additional pain relief.

If you have any other unusual or unexpected symptoms after receiving Sevoflurane anaesthesia, tell your doctor or anaesthetist **immediately**.

If you have any questions about Sevoflurane which are not answered by this leaflet, ask your doctor or anaesthetist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sevoflurane**Keep this medicine out of the sight and reach of children**

Do not use Sevoflurane after the expiry date which is stated on the carton and bottle label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage instructions.

Any unused product or waste material will be disposed of by a healthcare professional in accordance with local requirements.

6. Contents of the pack and other information**What Sevoflurane contains**

Sevoflurane 100% Inhalation Vapour, Liquid contains the active ingredient sevoflurane 100% v/v. There are no other ingredients.

What Sevoflurane looks like and the contents of the pack

Sevoflurane is a clear, colourless inhalation vapour, liquid.

It is supplied in Type III amber glass bottles sealed with a poly-seal cap, secured with PET film containing 250 ml.

Pack sizes of 1 and 6 bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland.

Manufacturer:

Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland
and/or

Pharmadox Healthcare Limited, KW20A Corradino Industrial Estate, Paola PLA3000, Malta.

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