

Package leaflet: Information for the user
Sevorane 100% v/v Inhalation Gas
(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 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 Sevorane is and what it is used for
2. What you need to know before receiving Sevorane
3. How Sevorane is given
4. Possible side effects
5. How to store Sevorane
6. Contents of the pack and other information

1. What Sevorane is and what it is used for

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

Sevorane 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 Sevorane is used in dental operations these must be performed in a hospital or day care unit.

2. What you need to know before receiving Sevorane

Do not receive Sevorane;

- 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 Sevorane.
- if you or any member of your family has experienced a condition called malignant hyperthermia (rapid rise in body temperature) during an operation with Sevorane 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 Sevorane 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 Sevorane 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 heart beats and changes in your heart electrocardiogram) or torsade de pointes (a special kind of irregular heart beat).
- you are prone to or at risk for 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 Sevorane.

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

- have seizures or seizure disorder (fits), as Sevorane may increase the risk of seizures.
- have Pompe's disease (a metabolic disorder). Sevorane 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 Sevorane

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.

Sevorane with alcohol

Alcohol should be avoided when taking Sevorane.

Pregnancy and breast-feeding

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

Driving and using machinery

Sevorane 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 Sevorane is given

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

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

The dose of Sevorane 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 Sevorane, 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 Sevorane than you should have been given

As Sevorane is given to you by an anaesthetist, an overdose is unlikely but if this were to occur, your 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 the 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 Sevorane 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

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Sevorane

Keep this medicine out of the sight and reach of children

Do not use Sevorane 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 will be disposed of by a healthcare professional in accordance with local requirements.

6. Contents of the pack and other information

What Sevorane contains

Sevorane Inhalation Gas contains the active ingredient sevoflurane 100% v/v.

The other ingredient is water.

What Sevorane looks like and contents of the pack

Sevorane Inhalation Gas is a non-flammable, volatile liquid for administration as an inhalation anaesthetic. When it is put into a vaporiser it becomes a gas that mixes with the oxygen you will be breathing.

Sevorane is available in PEN bottles containing either 100ml or 250ml, with a roll on pilfer-proof cap (ROPP) or Quik-fil MkI or MkII. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder Ireland:
AbbVie Limited, Citywest Business Campus, Dublin 24, Ireland

Marketing Authorisation Holder Malta:
AbbVie Pharmaceuticals S.A., 41-45 Marinou Antypa Ave.,
141 21 Neo Irakleio, Greece

Manufacturer:

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