

INFORMATION FOR THE PATIENT

Sevoflurane 100% Inhalation Vapour, liquid

Sevoflurane

Read all of this leaflet carefully before you start using 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 or nurse.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

What is in this leaflet:

1. What Sevoflurane 100% Inhalation Vapour, liquid is and what it is used for
2. What you need to know before you are given Sevoflurane 100% Inhalation Vapour, liquid
3. How Sevoflurane 100% Inhalation Vapour, liquid will be given
4. Possible side effects
5. How to store Sevoflurane 100% Inhalation Vapour, liquid
6. Contents of the pack and other information

1. What sevoflurane 100% inhalation vapour, liquid is and what it is used for

The active ingredient in Sevoflurane 100% Inhalation Vapour, liquid is sevoflurane, which is a general anaesthetic used for surgical operations and other procedures.

It is an inhaled anaesthetic that is given to you as a vapour for you to breathe in.

It causes you to fall into a deep sleep (induction of anaesthesia). It also maintains a deep, painless sleep during which you can undergo surgery (maintenance of anaesthesia). You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you are given sevoflurane 100% inhalation vapour, liquid

Sevoflurane should be administered only by healthcare professionals appropriately trained in the administration of general anaesthesia under the supervision of or by an anaesthetist.

You should not be given Sevoflurane 100% Inhalation Vapour, liquid if any of the following applies to you, please tell your doctor if:

- There are medical reasons why you should not be given a general anaesthetic.
- You have been told previously that you should not receive general anaesthesia.
- You are hypersensitive (or allergy) to sevoflurane or other similar anaesthetic.
- You, or anyone in your family, are susceptible to a condition called malignant hyperthermia (rapid rise in body temperature and severe muscle contractions)

during anaesthesia.

- You have liver problems or if you have previously had general anaesthetics, particularly if repeated over a short period of time. Some anaesthetics can occasionally cause problems in the liver, which can cause yellowing of the skin and eyes (jaundice).
- You have ever had QT prolongation (prolongation of a specific time interval in an ECG) or torsade de pointes (a specific type of heart rhythm), which may also be associated with QT prolongation. Sevoflurane has sometimes been known to cause these.
- You are prone to or at risk for seizures (fits).
- You have a mitochondrial disease.

Warnings and precautions

Talk to your doctor before taking Sevoflurane 100% Inhalation Vapour, liquid if:

- You have previously had general anaesthetics, particularly if repeated over a short period of time. You may have an increased risk of liver problems
- You are suffering from any illness, other than those connected with your operation, particularly any kidney or heart problems, low blood pressure, severe headaches, nausea or vomiting or Pompe's disease in children (a metabolic disorder). Sevoflurane may produce abnormal heart rhythms, which may be severe in some cases
- You have a certain type of muscle weakness (myasthenia gravis) because people with this disease are very sensitive to medicinal products that suppress breathing.
- You have a coronary artery disease
- You are hypovolaemic (reduced blood volume) or weak
- You suffer from a neuromuscular disease, particularly Duchenne muscular dystrophy
- You have raised pressure in the skull (intracranial pressure), such as from a head injury or brain tumour
- You have seizures or seizure disorders (fits), as sevoflurane may increase the risk of seizures.
- You are pregnant or breastfeeding children
- You have Down syndrome

If any of the above apply to you check with your doctor, nurse or pharmacist. You may need to be checked carefully and your treatment may be changed.

The following effects may occur during or after Sevoflurane 100% Inhalation Vapour administration:

- During the period in which you are anesthetized (induction phase), sevoflurane, as well as medicinal products that resemble it (halogenated anesthetics), may induce coughing. This must be taken into account.
- As with other anesthetics, minor mood changes may occur for a number of days after sevoflurane administration.
- Young children under the age of six are more likely to experience acute confusion (delirium) when waking up from anesthesia. In addition, children under the age of six are more likely to experience agitation/anxiety when waking up from anesthesia.
- In sensitive patients, anesthetics given by inhalation (inhalation anesthetics) may cause an increased metabolic (hypermetabolic) state of the skeletal muscles. This leads to high oxygen requirements of your muscles due to too high levels of CO₂ in the blood (hypercapnia). In that case you may experience muscle stiffness (muscle rigidity), increased heart rate (tachycardia), increased breathing (tachypnea), blue discoloration of the lips, tongue, skin, and mucous

membranes (cyanosis), heart rhythm disturbances (arrhythmia), and/or unstable blood pressure.

- In rare cases, the use of inhaled anesthetics (inhaled anesthetics) has been associated with an increased potassium level in the blood fluid (increase in serum potassium levels) that have led to heart rhythm disturbances (arrhythmias) and death in children after surgery.
- Sevoflurane may cause respiratory depression, which may be increased by narcotic premedication or other medicinal products that cause respiratory depression. Respiration should be monitored and if necessary be supported.

Other medicines and Sevoflurane 100% Inhalation Vapour, liquid

Tell your doctor if you are taking or have recently taken any of the following:

The medicines or active substances contained in the medicines listed below may influence each other's effect when used together with Sevoflurane 100% Inhalation Vapour, liquid. Some of these medicines are given to you during your surgery by your anaesthetist, as indicated in the description.

- Amphetamines (stimulants): used to treat attention-deficit hyperactivity disorder (ADHD) or narcolepsy
- Medicines that affect the heart such as adrenaline or epinephrine
- Beta blockers (e.g. atenolol, propranolol): These are heart medicines often given to treat a high blood pressure.
- Alcohol
- Barbiturates (depressant)
- St. John's Wort (an herbal remedy used to help with depression)
- Decongestants (ephedrine): used as a decongestant and commonly found in cough and cold medicines
- Non-selective monoamine oxidase (MAO) inhibitors (a type of antidepressants)
- Calcium antagonists
- Verapamil: This is a heart medicine, and it is given to treat a high blood pressure or when you suffer from an irregular heart beat.
- Tranquillisers (benzodiazepines e.g. diazepam, lorazepam): These are sedative medicines, which have a calming effect. They are used when you feel nervous for instance before your surgery.
- Strong painkillers such as morphine or codeine
- Muscle relaxants (Non-depolarising e.g. vecuronium, pancuronium, atracurium and depolarising e.g. succinylcholine): These medicines are used during general anaesthesia to relax your muscles.
- Isoniazid, used to treat tuberculosis (TB)
- Isoprenaline
- Other anaesthetics, e.g. nitrous oxide: This is a medicine used during general anaesthesia that will cause you to sleep and will ease your pain, propofol, opioids (e.g. alfentanil and sufentanil): These medicines are strong pain killers and are often used during general anaesthesia as sevoflurane may affect the way they work if they are given at the same time.

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This also applies to herbal medicinal products, vitamins and minerals.

Sevoflurane 100% Inhalation Vapour, liquid with food and drink

Sevoflurane 100% Inhalation Vapour, liquid is a medicine to make and keep you asleep so you can undergo surgery. You should ask your doctor, surgeon or anaesthetist when and what you can eat or drink after you wake up.

Pregnancy and breast feeding

Tell your doctor or anaesthetist if you are pregnant or think you may be pregnant or are breast feeding. It is not known whether sevoflurane or its by-products are transferred into human milk. It is advisable to stop breast-feeding for 48 hours after sevoflurane administration and discard any milk that is produced during this period. You should not receive sevoflurane 100% Inhalation Vapour, liquid if you are pregnant unless it is essential.

The use of sevoflurane for anesthesia during a C-section is safe for you as well as for your baby. The safety of sevoflurane during contractions and natural birth has not been demonstrated. Like other anesthetics, sevoflurane may cause reduced respiration in neonates. Your doctor will determine whether you may use sevoflurane

Driving and using machines

Sevoflurane 100% Inhalation Vapour, liquid severely influences your ability to drive and operate tools. Do not drive or operate tools or machines until your doctor tells you it is safe. Receiving an anaesthetic may influence your alertness for several days. This may affect your ability to carry out tasks that require mental alertness.

Ask your anaesthetist when it will be safe for you to drive and use machines again.

3. How sevoflurane 100% inhalation vapour, liquid will be given

Sevoflurane 100% Inhalation Vapour, liquid will be given by a trained anaesthetist in a surgery or hospital. The anaesthetist will decide how much sevoflurane you need and when it is to be given. The dose will vary according to your age, weight, the type of surgery you need, and other medicines given to you during surgery.

Sevoflurane 100% Inhalation Vapour, liquid is changed to vapour (gas) in a vaporiser. You will breathe it in as a vapour.

It may be used to put you to sleep before your operation or, if you are put to sleep with an injection, it may be used to maintain anaesthesia during the operation.

Once the anaesthetist stops you from inhaling sevoflurane, you will wake up within a few minutes.

If you have any further questions on the use of this product, ask your anaesthetist, doctor or nurse.

If you receive more Sevoflurane 100% Inhalation Vapour, liquid than you should

Sevoflurane 100% Inhalation Vapour, liquid will be given to you by a healthcare professional and it is not likely that you will receive too much Sevoflurane 100% Inhalation Vapour, liquid. If you are given too much Sevoflurane 100% Inhalation Vapour, liquid, your anaesthetist will

take any necessary measures.

4. Possible side effects

Like all medicines, Sevoflurane 100% Inhalation Vapour, liquid can cause side effects, although not everybody gets them. It is however, important to consult your ward doctor, nurse or anaesthetist if you are feeling unwell.

Serious rare side effects (can be life-threatening):

- Anaphylaxis and anaphylactoid reactions (see not known side effects section for more information).

The following side effects are serious and you may need immediate medical attention. Hospital staff will monitor you throughout your anaesthesia and will give immediate assistance when necessary.

Tell the doctor or nurse immediately if you have any of the following:

- Allergic reactions, which can be severe, with swelling of the face, tongue and throat and difficulty breathing.
- Malignant hyperthermia (very high temperature), which may require intensive care and may be fatal. This condition may run in families.
- Increased potassium levels in the blood (hyperkalaemia), which may result in abnormal heart rhythms and can be fatal in children during the post-operative phase. This has been seen in patients with neuromuscular disease, particularly Duchenne muscular dystrophy.

If you experience any of the following, tell your doctor or nurse:

Very common side effects (may affect more than 1 in 10 people)

- restlessness (agitation) in children
- slow heart rate (bradycardia)
- low blood pressure
- coughing
- nausea and vomiting.

Common side effects (may affect up to 1 in 10 people)

- headache
- drowsiness
- dizziness
- fast heart rate
- increased blood pressure
- breathing disorder
- airway obstruction
- slow and shallow breathing
- throat spasm, respiratory problems
- mouth watering
- hypothermia, chills

- fever
- abnormal blood sugar level, liver function test or white blood cell counts i.e. increased susceptibility to infections
- increased blood fluoride.

Uncommon side effects (may affect up to 1 to 100 people)

- confusion
- abnormal heart rhythm and abnormal heart beats
- AV blockade (a disorder of the electrical conduction of the heart)
- stopping breathing, low oxygen levels, fluid on the lungs
- retention of urine, glucose in the urine
- increased blood creatinine levels (an indicator of poor kidney function), as detected by a blood sample test.

Other side effects [frequency not known (frequency cannot be estimated from available data)]

- asthma
- allergic reactions e.g.:
- rash
- redness of the skin
- urticaria (hives)
- itching
- swollen eyelids, breathing difficulties
- anaphylaxis and anaphylactoid reactions. These allergic reactions occur quickly and can be life- threatening. Symptoms of anaphylaxis include:
- malignant hyperthermia
- angioedema (swelling of the skin of the face, limbs, lips, tongue or throat)
- breathing difficulties
- low blood pressure
- urticaria (hives)
- epilepsy-like fits
- sudden twitching movements
- cardiac arrest
- cramping of the airways
- difficulty in breathing or wheezing
- breath holding
- shortness of breath
- reduced liver function or hepatitis (inflamed liver), characterised by e.g. loss of appetite, fever, nausea, vomiting, abdominal discomfort, jaundice and dark urine.
- dangerously raised body temperature
- chest discomfort
- a rise in the pressure inside the skull
- irregular heart beat or palpitations
- inflammation of the pancreas
- Increases in blood potassium levels as detected by a blood sample test
- muscle stiffness

- inflammation of the kidneys (symptoms may include fever, confusion or sleepiness, rash, swelling, more or less urine than normal, and blood in the urine)
- swelling

Sometimes seizures (fits) are seen. These can occur when receiving Sevoflurane 100% Inhalation Vapour, liquid, or up to a day later during recovery. They occur mostly in children and young adults.

In children with Down Syndrome who receive sevoflurane, a slowing of the heart rate can occur. Children with Pompe's disease, a disease that they are born with, may have irregular heart rhythm during anaesthesia with sevoflurane.

Levels of fluoride in the blood may be raised slightly during and immediately after anaesthesia, but these levels are not thought to be harmful and soon return to normal. If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

If you notice any change in the way you feel after receiving sevoflurane, please inform your doctor or pharmacist. Some side effects may need treatment.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store sevoflurane 100% inhalation vapour, liquid

Keep out of the sight and reach of children.

Do not use Sevoflurane 100% Inhalation Vapour, liquid after the expiry date (MM-YYYY) which is stated on both the bottle label and carton. The expiry date refers to the last day of that month. The abbreviation, EXP is used for expiry date on the labels.

Store below 25 °C. Do not refrigerate. Keep the bottle tightly closed. Store upright.

6. Contents of the pack and other information

What Sevoflurane 100% Inhalation Vapour, liquid contains:

Sevoflurane 100% Inhalation Vapour, liquid contains 100% of the active ingredient sevoflurane. There are no other ingredients.

This medicine contains fluorinated greenhouse gases.

Each container contains 380 g of Sevoflurane corresponding to 0.0741 tone CO₂ equivalent (global warming potential GWP = 195).

What Sevoflurane 100% Inhalation Vapour, liquid looks like and contents of the pack:

Sevoflurane is a colourless liquid available in 250 ml amber coloured glass bottles (with or without an outer PVC coating) with either a screw cap or an integrated adaptor closure.

Pack sizes of 1 and 6 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Piramal Critical Care B.V.

Rouboslaan 32 (ground floor)

2252 TR

Voorschoten

Netherlands

Manufacturer

Piramal Critical Care B.V.

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2252 TR

Voorschoten

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OR

(For UK only)

Piramal Critical Care Limited

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Heathrow Boulevard - East Wing,

280 Bath Road, West Drayton,

UB7 0DQ,

United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria - Sevofluran Piramal 100 % Flüssigkeit zur Herstellung eines Dampfes zur Inhalation

Bulgaria - Sevoflurane Piramal 100% Inhalation Vapour, liquid

Cyprus - Sevoflurane – Piramal

Czech Republic - Sojourn 100% tekutina k přípravě inhalace parou

Denmark - SojournTM

Estonia - Sevoflurane- Piramal, inhalatsiooniaur, vedelik 100%

Germany - Sevofluran Piramal 100 % Flüssigkeit zur Herstellung eines Dampfes zur Inhalation

Greece - SojournTM Sevoflurane 100% Inhalation Vapour, liquid

Hungary - Sevoflurane Piramal folyadék inhalációs gőz készítéséhez

Iceland - Sevoflurane Piramal 100% innöndunargufa, vökvi

Ireland - Sevoflurane 100% Inhalation Vapour, liquid
Italy - Sevoflurane Piramal
Latvia - Sevoflurane Piramal 100 % Inhalation Vapour, liquid
Lithuania - Sevoflurane Piramal 100% inhaliaciniai garai skystis
Luxemburg - Sevoflurane 100%
Malta - Sevoflurane 100% Inhalation Vapour, liquid
Netherlands - Sevoflurane 100% (Piramal), Vloeistof voor inhalatiedamp
Norway - Sevoflurane Piramal væske til inhalasjonsdamp
Poland - Sojourn
Portugal - Sevoflurano Ojourn 100% líquido para inalação por vaporização
Slovenia - Sevofluran Piramal 250 ml para za inhaliranje, tekocina
Spain - Sevoflurano Piramal 100% líquido para inhalación del vapor
United Kingdom - Sevoflurane 100% Inhalation Vapour, liquid

This leaflet was last revised in:

Additional information for doctors or other healthcare professionals is included in the Summary of Product Characteristics for the product