

## **Package leaflet: Information for the user**

### **Sevoflurane Baxter 100% Liquid Inhalation Vapour**

Active substance: 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 pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Sevoflurane Baxter is and what it is used for**

Sevoflurane Baxter contains sevoflurane. Sevoflurane is a general anaesthetic used in surgery in adults and children. It is an inhalation anaesthetic (it is given to you as a vapour for you to breathe in). Breathing in sevoflurane vapour causes you to fall into a deep, painless sleep. It also maintains a deep, painless sleep (general anaesthesia) during which you can undergo surgery.

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 Baxter**

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

#### **Your anaesthetist (doctor) will not give you Sevoflurane Baxter if:**

- you are allergic (hypersensitive) to sevoflurane or other inhalation anaesthetics.
- you have a history of confirmed inflamed liver (hepatitis) due to sevoflurane or other inhalation anaesthetics or you have a history of unexplained liver problems with jaundice, fever, and an increased number of a certain type of white blood cells.
- you have a known or suspected susceptibility to malignant hyperthermia (a sudden and dangerously high increase in body temperature during or shortly after surgery).
- there are medical reasons why you should not be given a general anaesthetic

If any of the above applies, please inform your anaesthetist (doctor) before you are given this medicine.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Sevoflurane Baxter if:

- you have previously been given an inhalation anaesthetic, particularly if this was more than once over a short period of time (repeated use).
- you have low blood pressure

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- you are hypovolemic (reduced blood volume) or weak
  - you have impaired kidney function
  - you are pregnant or breastfeeding or when this medicinal product is given for obstetrical anaesthesia (delivery of a baby) (see also section entitled “Pregnancy and breastfeeding”)
  - you have a coronary artery disease
  - you have a risk of increased pressure within the brain
  - you have or previously had liver problems, e.g. hepatitis (inflamed liver) or jaundice
  - you are being treated with a medicine that may cause liver problems
  - you are known to have or are at risk of developing convulsions (seizures)
  - in the rare and unforeseen instance you develop malignant hyperthermia (a sudden and dangerously high increase in body temperature during or shortly after surgery). In this case your anaesthetist (doctor) will stop the administration of sevoflurane and you will be given a medicine to treat the malignant hyperthermia (known as dantrolene) and you will receive other supportive therapy. Fatal outcome of malignant hyperthermia has been reported with sevoflurane.
  - you have a neuromuscular disease e.g. Duchenne muscular dystrophy.
  - you have a disorder of the cells (a condition called mitochondrial disorder)

#### 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.

#### **Other medicines and Sevoflurane Baxter:**

Please inform your doctor, pharmacist, surgeon or anaesthetist if you are taking, have recently taken or might take any other medicines. This also applies to herbal medicinal products, vitamins and minerals.

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

- Nitrous oxide: This is a medicine used during general anaesthesia that will cause you to sleep and will ease your pain.
- Opioids (e.g. morphine, fentanyl, remifentanyl): These medicines are strong pain killers and are often used during general anaesthesia.
- Non-depolarising muscle relaxants (e.g. pancuronium, atracurium): These medicines are used during general anaesthesia to relax your muscles.
- 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.
- Adrenaline: This medicine is often used to treat allergic reactions, but can also be used during general anaesthesia.
- 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.
- Beta-blockers (e.g. atenolol, propranolol): These are heart medicines often given to treat a high blood pressure.
- Indirect sympathomimetic drugs e.g.: amphetamines (used to treat attention-deficit hyperactivity disorder (ADHD) or narcolepsy) or ephedrine (used as a decongestant and commonly found in cough and cold medicines)
- Isoniazid: A medicine used to treat tuberculosis (TB)
- Alcohol
- St John's Wort: this is a herbal remedy used for depression.

#### **Sevoflurane Baxter with food and drink**

Sevoflurane Baxter 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, breast-feeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor, surgeon or anaesthetist for advice before this medicine is given to you.

**Driving and using machines**

Sevoflurane Baxter 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 you will be given Sevoflurane Baxter**

Sevoflurane Baxter will be given to you by an anaesthetist. The anaesthetist will decide on how much 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 Baxter is produced from liquid sevoflurane in a vaporiser, specifically designed for use with sevoflurane. You may be asked to breathe the sevoflurane vapour through a mask to make you asleep. You may also be given an injection of another anaesthetic to make you sleep before being given sevoflurane Baxter through a mask or a tube in your throat.

Your anaesthetist will decide when to stop giving you Sevoflurane Baxter. You will then wake up in a few minutes.

**If you receive more Sevoflurane Baxter than you should**

Sevoflurane Baxter will be given to you by a healthcare professional and it is not likely that you will receive too much Sevoflurane Baxter. If you are given too much Sevoflurane Baxter, your anaesthetist will take any necessary measures.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate in their severity and are brief but there may be some serious side effects.

**Serious side effects (can be life-threatening)**

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

If these symptoms should occur whilst you are being given Sevoflurane Baxter, your anaesthetist will take appropriate action.

**Very common side effects (affects more than 1 user in 10)**

- agitation (being restless and disturbed).
- slower heart rate
- low blood pressure
- cough
- nausea (feeling sick) and vomiting (being sick)

**Common side effects (affects 1 to 10 users in 100)**

- drowsiness or feeling very sleepy
- headache
- dizziness
- fast heart rate

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- high blood pressure
  - breathing disorder
  - airway obstruction
  - slow and shallow breathing
  - throat cramping
  - increased salivation
  - fever
  - chills
  - increased or reduced number of white blood cells, which might affect the immune system, i.e. increased susceptibility to infections
  - increased level of glucose (sugar) in the blood, as detected by a blood sample test.
  - increases in liver enzymes, as detected by a blood sample test.
  - Increased level of fluoride in the blood, as detected by a blood sample test.
  - reduced body temperature

**Uncommon side effects (affects 1 to 10 users in 1,000)**

- confusion
- heart thumping or irregular heart beat
- AV blockade (a disorder of the electrical conduction of the heart)
- apnoea (when you stop breathing)
- asthma
- hypoxia (a low level of oxygen in the blood)
- increased blood creatinine levels (an indicator of poor kidney function), as detected by a blood sample test.

**Not known (frequency cannot be estimated from the available data)**

- allergic reactions e.g.:
  - rash
  - redness of the skin
  - urticaria (hives)
  - itching
  - swollen eyelidsbreathing difficulties
  - anaphylaxis and anaphylactoid reactions. These allergic reactions occur quickly and can be life-threatening. Symptoms of anaphylaxis include:
    - angioedema (swelling of the skin of the face, limbs, lips, tongue or throat)
    - breathing difficulties
    - low blood pressure
    - urticaria (hives)
- confused mental state
- 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
- yellow-looking skin

- 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 Baxter, 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.

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 gets 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, surgeon or anaesthetist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below).

United Kingdom:

Via the Yellow Card Scheme at: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store

Republic of Ireland:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store Sevoflurane Baxter**

Keep this medicine out of sight and reach of children.

Do not use Sevoflurane Baxter after the expiry date that is printed on the label. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

## **6. Contents of the pack and other information**

### **What Sevoflurane Baxter contains**

The active substance is sevoflurane 100% (250 ml in a 250 ml bottle).

There are no other ingredients.

### **What Sevoflurane Baxter looks like and contents of the pack**

Sevoflurane is a clear, colourless inhalation vapour, liquid.

It is supplied in 250 ml aluminium bottles with a protective lining.

The bottle may be closed with

- a plastic screw-on cap or
- an integrated valve that connects directly to an appropriate vaporiser.

Pack sizes of 1 and 6 bottles.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### MARKETING AUTHORISATION HOLDER

In the United Kingdom:

Baxter Healthcare Ltd

Caxton Way

Thetford, Norfolk IP24 3SE, UK

In Republic of Ireland:

Baxter Holding B.V.

Kobaltweg 49,

3542CE Utrecht,

Netherlands

#### MANUFACTURER

Baxter SA,

Boulevard Rene Branquart 80,

B-7860 Lessines,

Belgium

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Member State	Name
Austria	Sevofluran "Baxter" Flüssigkeit zur Herstellung eines Dampfs zur Inhalation
Belgium	Sevoflurane Baxter 100%, liquide pour inhalation par vapeur
Bulgaria	Sevoflurane Baxter 100%
Czech Republic	Sevoflurane Baxter
Denmark	Sevofluran "Baxter"
Estonia	Sevoflurane Baxter 100%
Finland	Sevofluran Baxter 100%, inhalaatiohöyry, neste
France	Sevoflurane Baxter 1 ml/ml, Liquide pour Inhalation par Vapeur
Germany	Sevofluran Baxter Flüssigkeit zur Herstellung eines Dampfs zur Inhalation
Hungary	Sevoflurane Baxter, folyadék inhalációs gőz készéséhez
Iceland	Sevofluran Baxter 100% innöndunargufa, vökvi
Ireland	Sevoflurane Baxter, 100%, inhalation vapour, liquid
Italy	Sevoflurane Baxter 100% Liquido per inalazione
Latvia	Sevoflurane Baxter 100% inhalācijas tvaiki, šķidrums
Lithuania	Sevoflurane Baxter 100% inhaliaciniai garai, skystis
Netherlands	Sevoflurane Baxter, vloeistof voor inhalatiedamp 100%
Norway	Sevofluran Baxter Væske Til Inhalasjonsdamp 100% "Baxter"
Poland	Sevoflurane Baxter 100% plyn do sporządzaniainhalacji parowej
Portugal	Sevoflurano Baxter
Romania	Sevofluran Baxter 100% lichid pentru vapori de inhalat
Slovak Republic	Sevoflurane Baxter
Slovenia	Sevofluran Baxter 250 ml para za inhaliranje, tekočina

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<b>Member State</b>	<b>Name</b>
Spain	Sevoflurano 100% Baxter, Líquido para inhalación del vapor
Sweden	Sevofluran Baxter, 100% inhalationsång, vätska
United Kingdom (Northern Ireland)	Sevoflurane Baxter 100% Inhalation Vapour, Liquid

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in March 2023

**Other sources of information**

For information about Sevoflurane Baxter or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 1635 206345

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