

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

### **Sevofluran Piramal 100% inhalation vapour, liquid**

**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, anaesthetist or nurse.
- If you get any side effects, talk to your doctor, anaesthetist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

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

#### **1. What <Invented name> is and what it is used for**

The drug substance is Sevoflurane. Sevoflurane belongs to a group of medicines called general anaesthetics. These work by temporarily reducing the activity of the body's central nervous system. This causes a complete loss of sensation in the body, including loss of consciousness allowing surgery to be carried out without pain and distress.

Sevoflurane is a clear colourless liquid, that when put into a special anaesthetic machine (vaporise) becomes a gas. This mixes with the oxygen you will be breathing in. Once breathed in (inhaled), sevoflurane will induce and maintain a deep, pain-free sleep (general anaesthesia) in adults and children.

#### **2. What you need to know before you are given <Invented name>**

**You or your child must not be given <Invented name> if:**

- you are allergic 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 doctor / anaesthetist before you or your child are given this medicine.

#### **Warnings and precautions**

Talk to your doctor or anaesthetist before you or your child are given <Invented name> 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;
- you are hypovolemic (reduced blood volume) or weak;
- you have impaired kidney function;

- this medicine is given for obstetrical anaesthesia (delivery of a baby) (see also section 3 “Pregnancy and breastfeeding”). Sevoflurane may cause increased blood loss after operations involving the womb;
- 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);
- you have a neuromuscular disease e.g. Duchenne muscular dystrophy;
- you have a disorder of the cells called mitochondrial disorder;
- 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 doctor / anaesthetist 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.

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

- suffer from Down syndrome;
- have Pompe’s disease (a metabolic disorder). Sevoflurane may produce abnormal heart rhythms, which may be severe in some cases.

#### **Other medicines and <Invented name>**

Tell your doctor, anaesthetist or nurse if you or your child are taking, have recently taken or might take any other medicines. This also applies to herbal medicines, 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. 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 medicine for your heart and it is given to treat a high blood pressure or when you suffer from an irregular heartbeat);
- Beta-blockers (e.g. atenolol, propranolol; these are medicines for your heart and often are given to treat a high blood pressure);
- Indirect sympathomimetics (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));
- St John’s Wort (this is a herbal remedy used for depression).
- MAO inhibitors (anti-depressants)
- Calcium antagonists (used to treat hypertension)

#### **<Invented name> and alcohol**

Alcohol should not be consumed before or after receiving this medicine.

### **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, surgeon or anaesthetist for advice before receiving this medicine. You should not receive sevoflurane if you are pregnant unless it is essential.

Caution should be exercised when sevoflurane is administered to nursing mothers as it is not known whether sevoflurane is present in human milk after anaesthesia.

### **Driving and using machines**

You should not drive or operate machinery after your operation or procedure, for which the anaesthetic has been administered, until your doctor advises that you may do so. Your ability to drive or operate machinery may be impaired for some time.

## **3. How you will be given <Invented name>**

<Invented name> will always be given to you by an anaesthetist. The anaesthetist will decide on how much you need and when it is to be given, according to your age, weight, the type of surgery you need, and other medicines given to you during surgery.

### **Inducing and maintaining sleep during anaesthesia**

<Invented name> is for inhalation use. It is given to you as a vapour for you to breathe in. The vapour is produced from liquid sevoflurane in a vaporiser, specifically designed for use with this medicine. 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 through a mask or a tube in your throat.

### **Waking-up after anaesthesia**

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

### **If you receive more <Invented name> than you should**

<Invented name> will be given to you by an anaesthetist and it is not likely that you will receive too much. If you are given too much sevoflurane, your anaesthetist will take any necessary measures.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. These can occur both during and after your operation.

### **Serious side effects:**

The following side effects with <Invented name> are serious and will be managed by your surgeon or anaesthetist, as necessary, during the operation. If you experience any of the following side effects after your operation, tell the doctor or nurse immediately:

- allergic reactions, anaphylactic reaction, which can be severe, with swelling of the face, tongue and throat and difficulty breathing;
- rapid rise in body temperature (malignant hyperthermia);
- wheezing and breathlessness.

### **Other side effects:**

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

- agitation (being restless and disturbed), slow heart rate, low blood pressure, cough, nausea (feeling sick) vomiting (being sick) and delirium (an acute mental condition causing confused thinking, reduced awareness of environment).

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

- drowsiness or feeling very sleepy, headache, dizziness, fast heart rate, 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 and reduced body temperature.

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

- a decrease or increase in the number of certain white blood cells. A decrease in the number of white blood cells may be associated with dizziness, fatigue, weakness, mouth ulcers and a tendency towards infections;
- confusion, heart thumping or irregular heartbeat, 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) and 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):**

- epilepsy-like fits, sudden twitching movements, cardiac arrest, reduced liver function or hepatitis (inflamed liver), characterised by e.g. loss of appetite, fever, nausea, vomiting, abdominal discomfort, jaundice and dark urine;
- chest discomfort, a rise in the pressure inside the skull, 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) and swelling.

Sometimes seizures (fits) are seen. These can occur when receiving sevoflurane, 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.

Other adverse effects

There may be very rare cases of spasmodic movements after sevoflurane anaesthesia. Such events were short-lived and there were no signs of illness during recovery from anaesthesia or after surgery.

**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 national reporting system** listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store <Invented name>**

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What <Invented name> contains**

The active substance is sevoflurane.

Each bottle contains 100% (V/V) sevoflurane.

There are no other ingredients.

This medicine contains fluorinated greenhouse gases.

Each container contains 380 g of Sevoflurane corresponding to 0.0741 tone CO<sub>2</sub> equivalent (global warming potential GWP = 195).

### **What <Invented name> looks like and contents of the pack**

<Invented name> is a clear, colourless inhalation vapour, liquid.

It is supplied in 250 ml amber coloured glass bottles (with or without an external PVC coating). The bottles are provided with an LDPE yellow-coloured collar and are closed with a two components screw cap (outer phenolic cover with LDPE liner).

Alternatively<Invented name>is supplied in 250 ml amber coloured glass bottles (with or without an external PVC coating) with a multicomponent screw cap (HDPE, ethylene propylene diene rubber (EPDM) o-rings/gaskets and stainless steel spring) attached to the bottle with an aluminium crimp ring.

Pack sizes of 1 and 6 bottles.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

<To be completed nationally>

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

Germany: Sojourn 100% Flüssigkeit zur Herstellung eines Dampfs zur Inhalation

Belgium: Sojourn 100%, Flüssigkeit zur Herstellung eines Dampfs zur Inhalation / Sojourn 100%, vloeistof voor inhalatiedamp / Sojourn 100%, liquide pour inhalation par vapeur

Finland: Sojourn 100% inhalaatiohöyry, neste

France: Sojourn 100%, liquide pour inhalation par vapeur

Sweden: Sevofluran Piramal 100% inhalationsånga, vätska

Slovak Republic: Sojourn 100% kvapalina na paru na inhaláciu

### **This leaflet was last revised in**

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