SEVOFLURANE SANDOZ®

Sevoflurane

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about SEVOFLURANE SANDOZ.

It does not contain all the information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SEVOFLURANE SANDOZ against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

WHAT SEVOFLURANE SANDOZ IS USED FOR

Sevoflurane belongs to a group of medicines called halogenated anaesthetic agents, which are breathed in to induce and/or maintain anaesthesia.

This medicine is administered by an anaesthetist in the air you breathe when you for surgery. It is a colourless liquid supplied in a bottle. It is given by your anaesthetist using a vaporiser, which turns the liquid into a gas so that you can breathe it in.

SEVOFLURANE SANDOZ is used for inducing and maintaining heavy sleep needed during surgery. The medicine produces loss of consciousness and pain sensations during surgery.

Ask your doctor if you have questions about why this medicine has been prescribed for you.

BEFORE YOU RECEIVE SEVOFLURANE SANDOZ

Before you are due to receive SEVOFLURANE SANDOZ

You must tell your doctor if

- 1. You have previously had any problems with a general anaesthetic.
- 2. You, or anyone in your family has malignant hyperthermia (a rare type of severe fever).
- 3. You have recently had any other general anaesthetic, or had more than one general anaesthetic over a short period of time
- 4. You have had SEVOFLURANE SANDOZ before and experienced an allergic reaction.
- 5. You have or have had the following medical conditions:
- Any problems with your liver including hepatitis
- Growths or abnormalities in your brain
- Heart disease; for example coronary artery disease, high or low blood pressure
- Lung problems, for example asthma

- Any problems with your kidneys
- Any problems with your nerves and muscles (neuromuscular disease)
- Mitochondrial disorders
- · Pompe's disease
- 6. You are on the following medications:
 - Muscle relaxants

 These medicines may affect the way your doctor gives you SEVOFLURANE SANDOZ.

 Tell your doctor also if you are taking any other medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.
- 7. You are pregnant or suspect you may be pregnant. The safety of SEVOFLURANE SANDOZ during pregnancy is
- not yet known.

 8. You are breast-feeding.

 It is not known whether

sevoflurane passes into breast milk. Your doctor will advise you on what to do it you are breastfeeding.

When you must not receive it

SEVOFLURANE SANDOZ should not be given to patients who are not suitable for receiving a general anaesthetic.
SEVOFLURANE SANDOZ should not be given to patients who are allergic or sensitive to halogenated anaesthetic agents.

Before SEVOFLURANE SANDOZ is started

SEVOFLURANE SANDOZ may cause drowsiness, tiredness or weakness for a while after it has been administered. It may also cause problems with coordination and ability to think. Therefore, for at least 24 hours (or longer if necessary) after receiving SEVOFLURANE SANDOZ, do not drive, operate moving machinery, or do anything else that could be dangerous if you are not alert.

Ask your doctor when you can drive and/or return to work involving machinery or heavy equipment.

Unless otherwise directed by your doctor, do not drink alcoholic beverages or take other central nervous system (CNS) depressants (medicines that may make you drowsy or less alert) for about 24 hours after you have received SEVOFLURANE SANDOZ. Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies or cold; other sedatives, tranquillisers or sleeping medicine, prescription pain medicine or narcotics; barbiturates; medicines for seizures; and muscle relaxants.

HOW SEVOFLURANE SANDOZ IS GIVEN

Only persons trained in the administration of general anaesthesia give SEVOFLURANE SANDOZ. It is given using a vaporiser. The dose of SEVOFLURANE SANDOZ will be adjusted to keep you at the right depth of sleep.

If you are given too much SEVOFLURANE SANDOZ

As SEVOFLURANE SANDOZ is given under strict supervision it is unlikely that you will receive too much. However, the anaesthetist can reduce the dose of SEVOFLURANE SANDOZ and provide oxygen should your blood pressure be too low or you have difficulty in breathing.

SIDE EFFECTS

As with all medicines, unwanted effects sometimes happen. Rarely SEVOFLURANE SANDOZ may produce unwanted effect, which you may wish to know about.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

SEVOFLURANE SANDOZ may cause some lowering of blood pressure and breathing rate, changes in heart rate or seizures. You will not know about these things since you will be asleep but your anaesthetist will adjust the dose of SEVOFLURANE SANDOZ as necessary and will give you other medicines if needed.

SEVOFLURANE SANDOZ may cause coughing, dizziness, drowsiness and increased salivation.

SEVOFLURANE SANDOZ may cause disturbances of liver function in some people. After your operation, tell your doctor if you develop the following symptoms of liver problems: nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions and/or dark coloured urine.

Some people may experience shivering, nausea and vomiting upon waking from the general anaesthesia. It is possible that SEVOFLURANE SANDOZ may cause a rare group of symptoms knowns as malignant hyperthermia. The features of this are muscle rigidity, fast pulse, breathing heavily and quickly, bluish lips and skin, changes in blood pressure and a fever. Your doctor will treat this by stopping SEVOFLURANE SANDOZ and using other medicines as needed. After anaesthesia there may be a brief rise in your white blood cell count. Your doctor will monitor this if it happens.

AFTER USING SEVOFLURANE SANDOZ

Storage

Store below 25°C. Store bottle in an upright position. It must be kept in the original container until immediately prior to use. Replace cap firmly in place after each use.

PRODUCT DESCRIPTION

What it looks like

SEVOFLURANE SANDOZ is a colourless liquid supplied in an amber bottle. Ingredients

Each bottle contains 250mL of the active substance sevoflurane.

Supplier

Sandoz Pty Ltd ABN 60 075 449 553 54 Waterloo Road Macquarie Park, NSW 2113 Australia Tel: 1800 726 369

Australian Registration Number:

SEVOFLURANE SANDOZ 1 mL/mL bottle AUST R 286635

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