

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

SEVONU Liquid

Sevoflurane

Read all of this leaflet carefully before you are given SEVONU

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or other healthcare provider.

What is in this leaflet

1. What SEVONU is and what it is used for
2. What you need to know before receiving SEVONU
3. How you will receive SEVONU
4. Possible side effects
5. How to store SEVONU
6. Contents of the pack and other information

1. What SEVONU is and what it is used for

SEVONU 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 or distress.

SEVONU is a clear colourless liquid, that when put into a special anaesthetic machine (vaporiser) becomes a gas. This mixes with the oxygen you will be breathing in.

Once breathed in (inhaled), SEVONU will induce and maintain a deep, pain-free sleep (general anaesthesia) in adults and children during an operation.



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2. What you need to know before receiving SEVONU

SEVONU should not be given to you:

- If you are allergic (hypersensitive) to sevoflurane or to any other inhaled anaesthetic.
- If you or any member of your family has had a condition called malignant hyperthermia (rapid increase in body temperature and severe muscle contractions) during an operation.
- If you have a neuromuscular disease, especially one called Duchene muscular dystrophy.

Warnings and Precautions

Tell your doctor or health care provider before receiving SEVONU:

- Tell your doctor, surgeon or anaesthetist if you are suffering from any illness, other than those connected with your operation, such as kidney, brain or heart problems, severe headaches, nausea, vomiting, or a neuromuscular disease (a condition that affects muscles e.g. Duchenne muscular dystrophy).
- 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. SEVONU has sometimes been known to cause these.
- If you have Pompe's disease (a metabolic disorder). Sevoflurane may produce abnormal heart rhythms, which may be severe in some cases.
- You have a mitochondrial disease, which is a disorder that people may be born with and may affect special cells of the heart, brain, and kidney.
- Tell your doctor, surgeon or anaesthetist if you have a liver condition or if you have previously been exposed to general anaesthetics, particularly if repeated over a short period of time. Some anaesthetics can cause problems in the liver which can cause yellowing of the skin and eyes (jaundice).
- If you have any other kidney problems.
- If you or your child are prone to or at risk for seizures (fits), as SEVONU may increase the risk of seizures.



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Other medicines and SEVONU

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This is particularly important if you are taking the following medicines:

- Sympathomimetic medicines such as isoprenaline, epinephrine/adrenaline and noradrenaline because it may cause changes in your heart rhythm.
- Amphetamines (stimulants).
- Non-selective monoamine oxidase (MAO) inhibitors (a type of antidepressants).
- Beta blockers, calcium antagonists or a medicine called verapamil (used to treat high blood pressure and certain heart conditions).
- Benzodiazepines and opioids.
- Isoniazid (an antibiotic used to treat tuberculosis).
- St John's Wort (a herbal medicine used to treat depression).
- Muscle relaxants such as pancuronium, vecuronium or atracurium.

Pregnancy, breastfeeding and fertility

Safety of SEVONU in pregnancy and breastfeeding has not been established.

The safety of SEVONU in labour and delivery has not been demonstrated.

SEVONU may be used for anaesthesia during Caesarean section.

If you are pregnant or could be pregnant or breastfeeding your baby while receiving SEVONU, it is important to consult your ward doctor, surgeon or anaesthetist.

It is not known whether SEVONU or its by-products are transferred into human milk. It is advisable to stop breast-feeding for 48 hours after SEVONU administration and discard any milk that is produced during this period.

If you are pregnant or breastfeeding; think you may be pregnant or are planning to have a baby, please consult your doctor or other health care provider for advice before being given this medicine.

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.



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3. How you will receive SEVONU

You will not be expected to give yourself SEVONU. It will be given to you by a person who is qualified to do so.

The dose of SEVONU that you receive will be decided by your anaesthetist and will vary depending on your age, weight and type of operation that you are having.

SEVONU is a breathed in (inhalation) anaesthetic gas. SEVONU liquid is changed to gas in a vaporiser. Occasionally, patients may be asked to breathe in the SEVONU gas via a mask but usually they will receive an injection of another anaesthetic to make them go to sleep before they receive SEVONU.

If you have the impression that the effect of SEVONU is too strong or too weak, tell your doctor or health care provider.

If you receive more SEVONU than you should

Since a health care provider will administer SEVONU, they will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you have missed a dose of SEVONU

Since a health care provider will administer SEVONU, it is unlikely that the dose will be missed.

4. Possible side effects

SEVONU can have side effects.

These side effects can occur both **during** and **after** your operation.

The following side effects with SEVONU are very serious and will be managed by your surgeon or anaesthetist, as necessary, during the operation. If you experience any of these side effects after your operation get medical help immediately:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SEVONU.

Other very serious side effects include:



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- Changes in the way your heart beats (beating faster, slower or irregular), irregular heartbeat or abnormal heart rhythm known as QT prolongation, heart attack, other heart disorders (AV block), which will be closely monitored by your anaesthetist during your operation and may be recognized by dizziness after your operation.
- Shortness of breath, difficulty breathing, coughing, wheezing (bronchospasm).
- Inflammation or damage to the liver. People with liver disease may have abdominal pain or fullness, dark urine, pale or white-coloured stool, yellowing of the eyes, nausea (feeling sick) and vomiting (being sick).
- Kidney failure. People with kidney disease may have tiredness, swelling or puffiness in the face, abdomen, thighs or ankles, passing less urine or problems urinating and back pain.
- Rapid rise in body temperature (malignant hyperthermia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following after surgery:

Frequent side effects:

- Restlessness (agitation).
- Drowsiness (somnolence), dizziness, headache.
- Low blood pressure (hypotension), high blood pressure (hypertension).
- Coughing, slow shallow breathing, throat spasm.
- Nausea (feeling sick), vomiting (being sick), watering mouth (salivary hypersecretion).
- Chills, fever.
- Increased blood sugar (glucose) level, abnormal liver function test, abnormal white blood cell count, increased blood fluoride.
- Low blood temperature (hypothermia).

Less frequent side effects:

- 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.
- Pauses in breathing, inadequate amount of oxygen, asthma.



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- Difficulty in passing urine, glucose in the urine if you have a urine test.
- Abnormal kidney function test results.

Side effects with unknown frequency:

- Convulsions (fits), twitching and jerking movements.
- Fluid in the lungs.
- Itching, skin rash, hives (urticaria).
- Muscle twitching.
- Chest discomfort.

Not all side effects reported for SEVONU are included in this leaflet. Should your general health worsen after taking SEVONU, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of SEVONU.

5. How to store SEVONU

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SEVONU contains:

The active substance is sevoflurane.



Sevoflurane Liquid for Inhalation 250mL
Lamar International (Pty) Ltd

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SEVONU does not contain any other ingredients.

What SEVONU looks like and contents of the pack

SEVONU is a clear, colourless, volatile liquid solution.

SEVONU is packed in 250 mL Type III amber glass bottles with a collar on the neck, sealed with a poly-seal cap, and secured with PET film.

Pack size: 1 x 250 mL bottle.

Holder of Certificate of Registration

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