

Package Leaflet: Information for the User
Suprane 100% Inhalation Vapour, Solution

Active substance: desflurane

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

In this leaflet:

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

1. What Suprane is and what it is used for

Suprane contains desflurane. Suprane is a general anaesthetic used in surgery. It is an inhalation anaesthetic (it is given to you as a vapour for you to breathe in). Breathing in desflurane 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. In adults, Suprane is used for induction and maintenance of anaesthesia. In intubated infants and children under 12 years, Suprane is used for maintenance of anaesthesia only. Intubation is when a tube is placed into the airways to help breathing. Suprane can sometimes be used for dental procedures in hospitals and day care units.

2. What you need to know before you are given Suprane

Your anaesthetist (doctor) will not give you Suprane if:

- you are a child to bring on (induce) anaesthesia. This is because using Suprane in this way can cause more unwanted side effects such as:
 - coughing
 - holding one's breath
 - stopping breathing (apnoea)
 - a muscle spasm of the vocal chords (voice box) called a laryngospasm
 - increased secretions in the airways
- you are allergic (hypersensitive) to desflurane or other inhalation anaesthetics such as isoflurane, sevoflurane, halothane and enflurane
- there are medical reasons why you should not be given a general anaesthetic
- you, or any relative suffer from a condition called malignant hyperthermia. Malignant hyperthermia is when you suddenly develop a dangerously high body temperature during or shortly after surgery in which you have received an anaesthetic by inhalation. Fatal outcome of malignant hyperthermia has been reported with desflurane.

- you have a history of confirmed liver disease (hepatitis) due to exposure to inhalation anaesthetics such as desflurane, isoflurane, sevoflurane, halothane and enflurane or a history of unexplained moderate to severe liver problems (hepatic dysfunction e.g. jaundice associated with fever and/or eosinophilia) after anaesthesia with desflurane or other inhalation anaesthetics such as isoflurane, sevoflurane, halothane and enflurane .
- you are undergoing Coronary Artery Bypass Graft surgery as a result of having coronary artery disease. This is when the blood vessels to your heart muscle do not deliver enough blood and oxygen.
- you are undergoing a dental procedure if it is to be performed outside a hospital or day care unit.
- your doctor considers that the likely side effects of Suprane are undesirable, like:
 - an increase in your heart rate
 - an increase in your blood pressure

If any of the above applies to you, please inform your doctor, surgeon or anaesthetist before you are treated with this medicine.

Warnings and precautions:

Your doctor will take special care when giving you Suprane if:

- you have a brain tumour
- following anaesthesia with Suprane in the past, you have had unexplained liver problems with:
 - jaundice (yellowing of the skin and white of the eyeballs)
 - fever
 - dead liver tissue (necrosis). This has been fatal in some cases.
- you have high blood sugar (diabetes). Suprane may increase your blood glucose levels during anaesthesia.
- 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 are at risk of bronchospasm (airway narrowing) or have neuromuscular disease (a disease of the nerves and muscles).
- you have an alteration of the electrical activity of your heart called "QT prolongation".
- you have coronary artery disease or are at risk of coronary artery disease, as a rapid increase in Suprane concentration may increase pulse rate and arterial blood pressure.

Your doctor may need to give you less Suprane if:

- you have a low blood volume (hypovolaemia)
- you have low blood pressure (hypotension)
- you are weakened (debilitated)

Your doctor may decide not to use Suprane if you have:

- cirrhosis (alcoholic liver disease)
- viral hepatitis (a liver disease caused by a virus)
- other types of liver disease

In this case your doctor may use a different type of anaesthetic.

Pain after your operation

You will recover from anaesthesia with Suprane quickly. If you are expected to have pain after your operation, your doctor will give you painkilling medicines. He may do this at the end of your operation or when you are recovering after your operation.

Your doctor should take particular care if you have previously been given an inhalation anaesthetic, particularly if this was more than once over a short period of time (repeated use).

Suprane can cause malignant hyperthermia (when you suddenly develop a dangerously high body temperature during or shortly after surgery).

Your doctor will make sure that the blood supply to your heart muscle is not affected during treatment.

Special information for the treatment of children

- Very rarely Suprane can cause problems with heart rhythm in children. This can result in death in the period immediately after the operation. These problems are seen in children that suffer from a disease of the nerves and muscles (neuromuscular disease), particularly a disease called 'Duchenne muscular dystrophy'. In most, but not all of these cases a muscle relaxant named suxamethonium was given at the same time.
- Desflurane should be used with caution in children with asthma or a history of recent upper airway infection due to the potential for airway narrowing and increases in airway resistance.
- Children may become agitated for a short time after waking up.
- Children under 12 years old will not be given Suprane to bring on (induce) anaesthesia. This is because using Suprane in this way can cause more unwanted side effects such as:
 - coughing
 - holding one's breath
 - stopping breathing (apnoea)
 - a muscle spasm of the vocal chords (voice box) called a laryngospasm
- increased secretions in the airways
- Children should not be given Suprane to maintain anaesthesia unless they have been intubated. Intubation is when a tube is placed into the airways to help breathing.

Due to limited data available, desflurane is not approved for maintenance of anaesthesia in children 12-18 years of age.

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

Taking other medicines and Suprane :

Tell your doctor, nurse, surgeon or anaesthetist if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription. 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 Suprane. Some of these medicines are given to you during your surgery by your anaesthetist, as indicated in the description.

- muscle relaxants (e.g. suxamethonium, pancuronium, atracurium, vecuronium): These medicines are used during general anaesthesia to relax your muscles. Your anaesthetist may need to adjust the dose of these medicines.
- opioids (e.g. fentanyl, morphine, remifentanyl): These medicines are strong pain killers and are often used during general anaesthesia.

- benzodiazepines (e.g. midazolam, diazepam, nitrazepam): These are sedative medicines, which have a calming effect. They are used when you feel nervous, for instance before your surgery.
- nitrous oxide: This is a medicine used during general anaesthesia that will cause you to sleep and will ease your pain.

Suprane with food and drink

Suprane 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

You should not be given Suprane if you are pregnant or if you are breast-feeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby consult your doctor, surgeon or anaesthetist.

Driving and using machines

Do not drive or operate tools or machines after your operation if you were given Suprane. Receiving an anaesthetic may influence your alertness. This may affect your ability to carry out normal tasks. You should not drive or operate tools or machines for 24 hours after your operation.

3. How you will be given Suprane

Suprane 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 and the type of surgery you need. Your anaesthetist will check your blood pressure and heart rate during your anaesthesia. This will help him to adjust your dose when necessary.

Suprane is produced from liquid desflurane in a vaporiser. You may receive Suprane in one of two ways:

- you may be given an injection of another anaesthetic to make you sleep before being given Suprane through a mask or a tube down your throat. This is the most common way that you may receive Suprane.

or

- you may be asked to breathe the desflurane vapour through a mask or a tube down your throat to make you sleep. You will fall asleep quickly and very easily. This is a less common way to receive Suprane.

After your surgery, your anaesthetist will stop giving you Suprane. You will then wake up in a few minutes.

If you receive more Suprane than you should

If you are given too much Suprane the medicine will be stopped. You will be given pure oxygen. Your blood pressure and heart function will be carefully checked while you recover.

4. Possible Side Effects

Like all medicines, this medicine can have 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.

The following side effects may also occur during treatment. The evaluation of the side effects is based on the following frequencies:

Very common (affects more than 1 user in 10):

- Nausea (feeling sick) and vomiting (being sick). These have occurred during induction and maintenance of anaesthesia with Suprane.

Common (affects 1 to 10 users in 100):

- Inflamed throat (pharyngitis)
- Breath holding. This has occurred during induction and maintenance of anaesthesia with Suprane.
- Headache
- Inflammation of the lining of the eyelid (conjunctivitis)
- Irregular heart rhythm (nodal arrhythmia)
- Slow heartbeat (bradycardia)
- Rapid heartbeat (tachycardia)
- High blood pressure (hypertension)
- Stopping breathing (apnoea); Cough; producing more saliva than usual (salivary hypersecretion). These have occurred during induction and maintenance of anaesthesia with Suprane.
- Muscle spasm of the vocal chords (voicebox) called a laryngospasm. This has occurred during induction of anaesthesia with Suprane.
- Increased blood levels of an enzyme called creatinine phosphokinase
- Abnormal heart tracing (abnormal ECG)

Uncommon (affects 1 to 10 users in 1,000):

- Restlessness (agitation)
- Dizziness
- Heart attack (myocardial infarction)
- Lack of blood flow to the heart muscle (myocardial ischemia)
- Irregular heart rhythm (arrhythmia)
- When your blood vessels widen (vasodilation)
- When your body is lacking an adequate oxygen supply (hypoxia). This has occurred during induction and maintenance of anaesthesia with Suprane.
- Muscle pain (myalgia)

Unknown frequency (frequency cannot be estimated from available data):

- Blood clotting disorder (coagulopathy)
- High blood levels of potassium (hyperkalemia)
- Low blood levels of potassium (hypokalemia)
- When your body produces too much acid (metabolic acidosis)
- Fits (convulsions)
- Yellowing of the eyeballs (ocular icterus)
- When the heart stops beating (cardiac arrest)
- A disorder of conduction of the heartbeat (torsade de pointes)
- When two of your heart's chambers stop working (ventricular failure)
- When two of your heart's chambers do not work so well (ventricular hypokinesia)
- Irregular heart beat (atrial fibrillation)
- Very high blood pressure (malignant hypertension)
- Bleeding (hemorrhage)
- Low blood pressure (hypotension)
- When your body tissues do not get enough blood (shock)

- Stopping breathing (respiratory arrest)
- When your breathing fails to provide enough oxygen for your body (respiratory failure/respiratory distress)
- Sudden spasm of the airways (bronchospasm)
- Coughing up blood (hemoptysis)
- Sudden inflammation of the pancreas (acute pancreatitis)
- Pain in the abdomen (abdominal pain)
- Liver failure (hepatic failure)
- Death of liver tissue (hepatic necrosis)
- Inflammation of the liver (hepatitis, cytolytic hepatitis)
- When the bile does not flow properly (cholestasis)
- Yellowing of the skin or the eyeballs (jaundice)
- Abnormal liver function (abnormal hepatic function)
- Liver disorder
- Hives (urticaria)
- Redness (erythema)
- A muscle disease (rhabdomyolysis)
- Malignant hyperthermia. This is when you suddenly develop a dangerously high body temperature during or shortly after surgery. Symptoms include:
 - too much carbon dioxide in the blood (hypercapnia)
 - muscle stiffness (rigidity)
 - increased heart rate (tachycardia)
 - increased breathing rate (tachypnoea)
 - blue coloured skin (cyanosis)
 - irregular heartbeats (arrhythmias)
 - increases or decreases in blood pressure
 - fever
- Weakness (asthenia)
- Feeling generally unwell (malaise)
- Changes to your heart tracing (electrocardiogram ST-T change)
- Changes to your heart tracing (electrocardiogram T wave inversion)
- Alteration of the electrical activity of your heart (QT prolongation)
- Increases in liver enzymes (alanine aminotransferase increased; aspartate aminotransferase increased)
- Increased Bilirubin levels in the blood
- Abnormal blood clotting (coagulation test abnormal)
- Levels of ammonia increased
- Increased blood sugar levels
- Agitation after the operation.
- Confused mental state

The following side effects have occurred after Suprane was given accidentally to non-patients.

- Dizziness
- Severe headache (migraine)
- Irregular and rapid heart beat (tachyarrhythmia)
- When you feel your heartbeat (palpitations)
- Eye burns
- Temporary blindness (transient blindness)
- Brain disorder (encephalopathy)

- Ulcer of the white (cornea) of the eye (ulcerative keratitis)
- Bloodshot eyes (ocular hyperemia)
- Sight problems (visual acuity reduced)
- Eye irritation
- Eye pain
- Tiredness (fatigue)
- Skin burning sensation

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Suprane

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

Do not use Suprane after the expiry date that is printed on the label after the term 'Use before'. The expiry date refers to the last day of that month.

This medicine requires no special storage conditions.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Suprane contains

The active substance is desflurane 100% (240 mL in a 250 mL bottle).

There are no other ingredients.

What Suprane looks like and contents of the pack

Suprane is a clear colourless to practically odourless solution (which is changed to a vapour or gas by an anaesthetic machine).

It is supplied in amber glass bottles with a protective PVC coating or aluminium bottles which are internally coated with epoxyphenolic resin.

The bottle is closed by a valve to connect with the vaporiser.

Not all pack sizes may be marketed.

MARKETING AUTHORISATION HOLDER

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

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For information about Suprane 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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