

PACKAGE LEAFLET

Package leaflet: Information for the user Desflurane 100%

(v/v) Inhalation vapour liquid Desflurane

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, pharmacist or nurse.
- This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Desflurane is and what it is used for

Desflurane Inhalation vapour liquid contains desflurane which belongs to the group of halogenated hydrocarbons. Desflurane is a colorless liquid used as 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 sleep. It also maintains a deep sleep (general anaesthesia) during which you can undergo surgery. In adults, desflurane is used for induction and maintenance of anaesthesia. In infants and children, it is used for maintenance of anaesthesia only.

2. What you need to know before Desflurane is used

Desflurane should be administered only by health care professionals adequately trained in the administration of general anaesthesia, under the supervision of an anaesthesiologist or by them.

Desflurane must not be used:

- if you have or have ever had medical reasons for not receiving general anaesthetics.
- if you are allergic to desflurane or to other halogenated anaesthetics such as isoflurane or sevoflurane.
- if you or any member of your family has experienced a rapid and significant rise in body temperature during an operation or soon after (a condition called malignant hyperthermia).
- to bring on (induce) anaesthesia if you are a child because of the significant risk of coughing, holding one's breath, stopping breathing, vocal cord spasm (laryngospasm) and increased secretions in the airways.
- if you are a child (under 6 years of age) to maintain anaesthesia unless you are intubated. Intubation is when a tube is placed into the airways to help breathing.
- as sole anaesthetic if you are at risk of increase in heart rate or blood pressure.
- if in the past you had been diagnosed with hepatitis or unexplained moderate or severe problems with liver function (e.g., jaundice with unexplained fever and/ or an increased number of certain white blood cells) after receiving inhalation anaesthetics such as isoflurane or sevoflurane.
- if you are undergoing dental procedures outside a hospital or day care unit.

Before receiving this medicine, tell your doctor or anaesthesiologist if any of the above applies to you.

Warnings and precautions

Talk to your doctor or anaesthesiologist before receiving Desflurane:

- if you have a risk of increased pressure inside the head e.g. brain tumour.
- if you have a tendency to suffer from bronchoconstriction (a tightening of the lungs and airways leading to coughing, wheezing or shortness of breath).
- if you are at a risk for coronary artery disease (when the blood vessels do not transport enough blood and oxygen to the heart muscle).
- if you are pregnant or breast feeding, or if this medicine is administered during delivery (also see “Pregnancy and breast-feeding”).
- if you suffer from a condition that affects the muscles (a neuromuscular disease such as Duchenne muscular dystrophy). You may be given a muscle relaxant at the same time as desflurane.
- You have a disturbance in the electrical activity of your heart called “QT interval prolongation”.
- if you have previously received general anaesthetics, especially if given multiple doses over a short time period.
- If you are a child with a recent infection of respiratory tract.

Your doctor may administer less Desflurane:

- in case of a low blood volume (hypovolemia).
- in case of a low blood pressure (hypotension).
- in case of weakness.

Your doctor can decide not to give you Desflurane and will choose another type of anaesthesia:

- if you have liver disease due to alcohol abuse (cirrhosis).
- if you have viral hepatitis (a virus-induced liver disease).
- if you have other types of liver diseases. (e.g. unexplained liver problems after anaesthesia, such as jaundice (yellow skin and eyes)
- fever
- hepatocellular necrosis.

Desflurane can cause a rapid and significant rise in body temperature accompanied by muscle stiffness and other symptoms during an operation (malignant hyperthermia). In this case, the anaesthesiologist (doctor) will stop administering Desflurane, you will be given a medicine to treat malignant hyperthermia (known as dantrolene) and you will receive another maintenance therapy.

Your doctor must proceed with special care if an inhalational anaesthetic medicine was administered previously especially if it was multiple times during a short time interval (repeated use).

After anaesthesia with desflurane you will wake up again quickly. If pain is anticipated after the operation, your doctor will give you a painkiller. Your doctor can do this either at the end of the operation or during the recovery phase.

Desflurane can cause a slight increase in blood sugar level during anaesthesia.

Middle ear surgeries

Desflurane, as well as other volatile anaesthetics increase middle ear pressure especially in children, and hence it is recommended that middle ear pressure be monitored during anaesthesia with desflurane.

Children

- Desflurane should be used with caution in children with asthma or a history of recent upper respiratory tract infection due to the potential for airway narrowing and increases in airway resistance.
- Desflurane must not be used to induce anaesthesia in infants (refer also to section 2)
- Waking up from anaesthetics can cause a brief state of agitation in children, which makes them uncooperative.

- Desflurane can be given for maintenance of anaesthesia only if a breathing tube is placed into the airway to help breathing (intubation). In these cases, caution should be exercised when removing the laryngeal mask after deep anaesthesia to avoid side effects, such as cough or muscle spasm of the vocal cords called laryngospasm.

If any of the above conditions 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

Other medicines and Desflurane

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

Special care is required if any of the following medicines are being taken:

- Muscle relaxants (such as Suxamethonium, Pancuronium, Atracurium, Vecuronium). These medicines help to relax the muscles. The anaesthesiologist might possibly adjust the dosage.
- Opioids (such as Fentanyl, Morphine, Remifentanyl). These medicines are strong painkillers and frequently used during full anaesthesia. Please inform your doctor even if you use these painkillers at other times.
- Benzodiazepines (such as Midazolam, Diazepam, Nitrazepam). These are tranquilisers, used to relax a patient who is agitated before surgery. Please inform your doctor even if you use these sedatives at other times.
- Nitrous oxide (laughing gas). This medicine can be used during full anaesthesia so that the patient sleeps and eases pain.

Using Desflurane with food and drink

Desflurane is a medicine to put you to sleep 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 before anaesthesia and after you wake up.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor or pharmacist before being given this medicine.

There are no adequate data from the use of desflurane in pregnant or lactating women. Therefore desflurane should only be used in pregnant and breast-feeding women when considered absolutely necessary. Breast-feeding should be avoided after anaesthesia with desflurane for about 24 hours.

Driving and using machines

Desflurane can affect your alertness and ability to respond for some time after receiving the medicine. Therefore, do not drive or operate machinery for 24 hours after your operation.

3. How to use Desflurane

Desflurane must be used under cardiorespiratory supervision and in the presence of an anaesthetist doctor with technical means allowing anaesthesia and resuscitation. Desflurane will always be administered to you by an anaesthesiologist. The anaesthesiologist will decide on the dose you will receive depending on your age, body weight and the type of operation you are having. During anaesthesia, the anaesthesiologist will check your blood pressure and heart rate. If required, the anaesthesiologist will adjust your dose.

Most commonly Desflurane is administered through a tube which is placed into the airways after you have been given an injection of another anaesthetic that induces sleep. Only in rare cases you may be asked to breathe in the desflurane vapours through a mask to induce sleep.

Desflurane is a liquid for vapor inhalation that is administered via a vaporizer specifically calibrated for use of this product, so that the concentration delivered can be accurately controlled

Waking-up after anaesthesia

After the operation, the anaesthesiologist stops giving you desflurane. You will wake up within a few minutes.

If you receive more Desflurane than you should

If you receive more desflurane than you should, administration is stopped. Pure oxygen will be provided. Your blood pressure and heart function will be carefully checked while you wake up.

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

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 severity and last a short time. However, some side effects can also be serious (severe)

Serious side effects (Frequency not known) such as:

- Muscle fibre breakdown (rhabdomyolysis),
- Irregular heartbeat or abnormal heart rhythm (arrhythmia) in children.
- Rapid and significant rise in body temperature during an operation (malignant hyperthermia). The signs of illness include: Excess carbon dioxide in the blood (hypercapnia), Muscle stiffness (rigidity), Increased heartbeat (tachycardia), Increased breathing (tachypnea), Blue colouration of the skin (cyanosis), Irregular heartbeat or abnormal heart rhythm (arrhythmia), Low or high blood pressure and fever

Most of these serious side effects can occur while you are under anesthesia and in the care of healthcare professionals.

Desflurane can cause a slight increase in the level of the blood sugar during anaesthesia. Possible side effects include:

Very common (may affect more than 1 in 10 patients)

- Nausea
- Vomiting

These occur during induction and maintenance of anesthesia with desflurane.

Common (may affect up to 1 in 10 patients)

- Inflammation of the back of the throat (pharyngitis)
- Temporary breath holding. This has occurred during induction and maintenance of anesthesia with desflurane.
- Headache
- Inflammation of the outer layer of the eye and inner surface of the eyelids (conjunctivitis)
- Irregular heartbeat or abnormal heart rhythm
- Slower heartbeat (bradycardia)
- Faster heartbeat (tachycardia)
- High blood pressure (hypertension)
- Temporary stopping breathing (apnoea), cough and excessive saliva production (salivary hypersecretion). These have occurred during induction and maintenance of anesthesia with desflurane.
- Sudden spasm of the vocal cords that affects breathing and speaking (laryngospasm)
- Increased blood counts of certain enzymes called creatine phosphokinase
- Abnormal recording of the heartbeat (abnormal ECG).
- Heart rhythm abnormal (Prolongation of QTc interval abnormal ECG)

Uncommon (may affect up to 1-10 in 1000 patients)

- Restlessness (Agitation)
- Dizziness
- Heart attack (myocardial infarction)

- Reduced blood flow to the heart muscle (myocardial ischemia)
- Irregular heartbeat (arrhythmia)
- Enlarged blood vessels (vasodilatation)
- Reduced oxygen supply (hypoxia). This may occur during induction and maintenance of anesthesia with desflurane.
- Muscle pain (myalgia)

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

- Blood clotting disorder (coagulopathy)
- Increased or decreased levels of potassium in the blood (hyperkalemia / hypokalemia)
- Too much acid in the body fluids (metabolic acidosis)
- Seizures (convulsions)
- Yellowing of the eyeball (ocular icterus)
- Heart failure (when the heart is having difficulty beating) or cardiac arrest (when the heart stops beating)
- severe heart rhythm disturbances with fast, irregular pulse (torsade de pointes)
- Ventricular malfunction (when two of your heart's chambers do not work so well or they stop working)
- Reduced heart muscle contraction (ventricular hypokinesia)
- Irregular heart beat (atrial fibrillation).
- Very high blood pressure (malignant hypertension)
- Bleeding (haemorrhage)
- Low blood pressure (hypotension)
- When your body tissues do not get enough blood (shock)
- Difficulty breathing (respiratory failure) or stopping breathing (respiratory arrest)
- Sudden tightening of muscles in the airways (bronchospasm)
- Coughing up blood from the lungs (haemoptysis)
- Sudden inflammation of the pancreas (acute pancreatitis)
- Stomach pain (abdominal pain)
- Death of liver tissue (hepatic necrosis)
- Inflammation of the liver (Hepatitis)
- Blocked flow of bile from the liver (cholestasis)
- Yellowing of the skin or eyeball (jaundice)
- Disturbances in liver function or liver disease
- Hives (urticaria)
- Redness of the skin (erythema)
- Feeling of weakness (asthenia)
- General discomfort
- Changes in the recording of the cardiac activity (changes of the ST-T-measurements or inversion of the T wave in the ECG)
- Increase in the liver enzymes (increased alanine- or aspartate-aminotransferase values)
- Blood clotting disorder (abnormal clotting values)
- Increased ammonia values
- Elevated levels of bilirubin increased
- Liver failure
- Sensation of whirling and loss of balance (Vertigo)
- Palpitations
- Burning sensation in the eyes
- Temporary blindness
- Brain disease (encephalopathy)
- Inflammation or infection of part of the eye (ulcerative keratitis)
- Bloodshot eyes (ocular hyperemia)
- Reduced visual sharpness and clarity

- Eye irritation
- Eye pain
- Fatigue
- Burning sensation of the skin
- Postoperative agitation.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

Tell your doctor, pharmacist or nurse if you notice any changes in the way you feel after receiving desflurane. Some side effects may require treatment.

5. How to store Desflurane

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 label, after 'EXP.'. The expiry date refers to the last day of that month.

Store below 30°C.

Store the bottle in the upright position with the cap tightly closed.

6. Contents of the pack and other information What Desflurane contains

- The active substance is desflurane 100% (v/v).
- There are no other ingredients.

What Desflurane looks like and contents of the pack

Desflurane is an inhalation vapour liquid. Desflurane is a clear, colourless liquid.

250 mL amber Type III glass bottle, and PVC coating on the outside of the bottle with HDPE / Ethylene Propylene Diene Monomer (EPDM) closure and an aluminium crimp

Pack sizes of 1 and 6 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder Piramal Critical Care Limited Suite 4, Ground Floor
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Manufacturer

Piramal Critical Care B.V.

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This medicine has been authorised in the Member States of the EEA under the following names:

Austria	: Desfluran Piramal 100 % Flüssigkeit zur Herstellung eines Dampfes zur
Belgium	: FR: Desflurane Piramal 100 % liquide pour inhalation par vapeur NL: Desfluraan Piramal 100 %, vloeistof voor inhalatiedamp. DE: Desfluran Piramal 100 %, Flüssigkeit zur Herstellung eines Dampfes zur Inhalation.
Denmark	: Desfluran Piramal 100 % Væske til inhalationdamp
Finland	: Desfluraani Piramal
France	: DESFLURANE PIRAMAL 100% liquide pour inhalation par vapeur
Germany	: Desfluran Piramal 100 %, Flüssigkeit zur Herstellung eines Dampfes zur
Hungary	: Dezflurán Piramal 100% folyadék inhalációs gőzképzéséhez
Italy	: Desflurano Piramal
Netherlands	: Desfluraan Piramal 100 % vloeistof voor inhalatiedamp
Norway	: Desfluran Piramal
Poland	: Desfluran Piramal
Portugal	: Desflurano Piramal 100% líquido para inalação por vaporização
Spain	: Desflurano Piramal 100% Líquido para inhalación del vapor
Sweden	: Desfluran Piramal 100 % inhalationsång, vätska
United	: Desflurane 100% (v/v) Inhalation Vapour, liquid

This leaflet was last revised in 03/2024