

## Package leaflet: Information for the user

### Desflurane 100% 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, 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 Desflurane is and what it is used for
2. What you need to know before you are given Desflurane
3. How Desflurane is given
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 contains desflurane. Desflurane 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 sleep. It also maintains a deep sleep (general anaesthesia) during which you can undergo surgery. Desflurane is indicated as an inhalation agent for maintenance of anaesthesia for inpatient and outpatient surgery in intubated adults, infants and children.

#### 2. What you need to know before you are given Desflurane

##### Desflurane must not be given:

- if you have or have ever had medical reasons for not receiving general anaesthetics.
- if you are allergic to halogenated anaesthetics.
- if you or any member of your family has experienced a rapid and significant rise in body temperature during an operation (a condition called malignant hyperthermia).
- if you are an adult, child or infant to maintain anaesthesia unless you are intubated. Intubation is when a tube is placed into the airways to help breathing.
- if in the past after receiving inhalation anaesthesia, you had problems with liver function (e.g. jaundice associated with fever and/or eosinophilia), unexplained fever or an increased number of certain white blood cells (leukocytosis).
- if you are undergoing dental procedures outside a hospital or day care unit.

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

##### Warnings and precautions

Talk to your doctor or anaesthetist before receiving Desflurane:

- if you have a risk of increased pressure inside the head.
- 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.
- 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.
- if you have an alteration of the electrical activity of your heart (QT prolongation).

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.

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.

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).

Desflurane can cause a rapid and significant rise in body temperature during an operation (malignant hyperthermia).

##### Children

This medicine should not be given to children and infants to bring on (induce) anaesthesia. This is because using Desflurane 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 under 6 years old should not be given Desflurane to maintain anaesthesia unless they have been intubated. Intubation is when a tube is placed into the airways to help breathing.

##### 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.

##### Other medicines and Desflurane

Tell your doctor or anaesthetist 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 anaesthetist might possibly adjust the dosage.
- Opioids (such as Fentanyl, Morphine, Remifentanyl). These medicines are strong painkillers and frequently used during full anaesthesia.
- Benzodiazepines (such as Midazolam, Diazepam, Nitrazepam). These are tranquilisers, used to relax a patient who is agitated before surgery.
- Beta Sympathomimetics (isoprenaline) and alpha- and beta-agonists (epinephrine, or adrenalin; norepinephrine or noradrenaline).
- Nitrous oxide (laughing gas). This medicine can be used during full anaesthesia so that the patient sleeps and eases pain.

##### Pregnancy and breast-feeding

Desflurane is a uterine relaxant and reduces the uterine-placental blood flow. There are no adequate and well-controlled studies in pregnant women. Limited animal data do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Since animal studies are not always predictive of human response, Desflurane should be used during surgeries in pregnant women after the potential risks and benefits are weighed for each patient.

There are no adequate data from the use of Desflurane in breast-feeding women and it is not known whether the drug passes into breast milk. Before prescribing Desflurane, anaesthetist should carefully weigh the potential risks and benefits for each patient.

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

##### 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 Desflurane is given

Desflurane will always be administered to you by an anaesthetist. The anaesthetist 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 anaesthetist will check your blood pressure and heart rate. If required, the anaesthetist 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 vapors through a mask to induce sleep.

##### Waking-up after anaesthesia

After the operation, the anaesthetist 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, anaesthetist 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.

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 people)

- Nausea
- Vomiting

##### **Common** (may affect up to 1 in 10 people)

- Inflammation of the back of the throat (pharyngitis)
- Temporary breath holding
- 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
- 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)
- Prolongation of QTc interval (abnormal ECG)

##### **Uncommon** (may affect up to 1 in 100 people)

- 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)
- 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)
- Life threatening irregular heart beat (torsades-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)
- 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 (cytolytic 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)
- Muscle fibre breakdown (rhabdomyolysis)
- 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

- 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
- Postoperative agitation

##### **Accidental exposure**

The following side effects occurred in patients who were accidentally exposed to Desflurane:

- Dizziness
- Severe headache (migraine)
- Irregular, faster heartbeat (tachyarrhythmia)
- 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

##### **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 the Yellow Card Scheme at Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

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

#### **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.

No special storage conditions.  
Store in an upright position with cap firmly in place. Replace after each use.

#### **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-colored plastic coated glass bottles containing 240ml of desflurane, sealed with a semitransparent valve assembly and aluminum ferrule, and secured with PET sealing film.

Packaged product is supplied in boxes of 6.

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

###### **Marketing Authorisation Holder**

Cadiusun Pharma GmbH  
Lendersweg 27, 47877 Willich,  
Germany

###### **Manufacturer**

Pharma Pack Hungary Limited  
Vasút utca 13, Budaörs, 2040,  
Hungary

Quercus Labo BV  
Wijmenstraat 21P,  
Mariakerke, 9030,  
Belgium

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