

# Medical Oxygen - Package Leaflet: Information for the User

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 or pharmacist. This medicine has been prescribed for you only. Do not pass it on 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

## What is in this leaflet:

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

## 1. What Medical Oxygen is and what it is used for

Medical Oxygen is a breathed in (inhalation) gas. It is colourless, odourless and tasteless. It is supplied under pressure in a cylinder with a valve to control the outflow of gas. A variety of cylinder sizes are available.

### What Medical Oxygen is used for

Medical oxygen is used to increase levels of oxygen in the body's tissues. It may be used in the following circumstances:

- at high concentrations when there is a reduced amount of oxygen being taken into the body through the lungs due to acute or severe asthma or lung disease such as pulmonary thrombo-embolism (a blockage of one of the arteries in the lung), pneumonia, fibrosing alveolitis (inflammation and scarring of the air sacs of the lungs and pulmonary oedema (a disease affecting the heart))
- in low concentrations when there are breathing difficulties due to conditions such as in chronic obstructive airways disease (COAD/COPD) (a collection of lung diseases caused by damage to the lungs)
- in the treatment of acute and severe asthma, sleep apnoea (a sleep disorder in which a person has irregular breathing at night and is excessively sleepy during the day), cluster headaches (attacks of severe one sided headaches over several weeks), shock (a dramatic reduction in blood flow that if left untreated can lead to collapse, coma and even death) and in other situations where localised blood supply is poor
- for resuscitation purposes by trained persons, where oxygen supply to the body is reduced due to a medical emergency
- when the oxygen capability of the blood is reduced such as in carbon monoxide poisoning or severe anaemia (a condition which occurs when there is a reduced number of red blood cells or haemoglobin concentration)
- when gas is trapped in body spaces such as in pneumothorax (air is trapped next to a lung resulting in collapse of the lung) or air embolism or other gas disturbances such as decompression sickness (associated with diving)
- as a carrier gas in anaesthesia or as a diluent for anaesthetic gases or vapours

## 2. What you need to know before you use Medical Oxygen

### Do not use Medical Oxygen

Oxygen at a pressure greater than atmospheric pressure (Hyperbaric Oxygen Therapy) must not be used in cases of untreated/undrained pneumothorax. A pneumothorax is due to the accumulation of air in the thoracic cavity between the two pulmonary membranes. If you have ever had a pneumothorax, please let your doctor know.

### Warnings and precautions

Talk to your doctor or pharmacist before using Medical Oxygen.

Before to start the oxygen therapy, you should know the following:

- Oxygen may have harmful effects at high concentrations. This may cause pulmonary damages (collapse of the alveoli, inflammation of the lung), which will obstruct the oxygen supply to the blood.
- If you have a severe chronic obstructive pulmonary disease (COPD) with subsequent deficiency in blood oxygenation, the flow rate of oxygen will be low. The doctor will adapt the appropriate flow rate of oxygen therapy.
- Adverse events such as eye damage may occur in new-born infants and pre-term new-born infants. If your baby requires extra oxygen, the doctor will determine the appropriate concentration of oxygen to be administered.

Hyperbaric oxygen therapy requires precautions in case of:

- **chronic obstructive pulmonary disease (COPD)**
- **lung emphysema:** a disorder of the lungs due to the loss of elasticity of lung tissue accompanied by (serious) shortness of breath
- **infections in the upper respiratory tract**
- insufficiently controlled **asthma**
- recent **middle ear surgery**
- recent **thoracic surgery**
- **uncontrolled high fever**
- **history of epilepsy or convulsions**
- **fear of confined spaces** (claustrophobia)
- if you have ever had a **pneumothorax** which is an accumulation of air or gas in the thoracic cavity between the two pulmonary membranes
- **heart problems**

### Advice regarding the increased risk of fire in presence of oxygen:

- Oxygen is an oxidising product and promotes combustion. There must be no smoking or open flames (e.g. pilot lights, cookers, oven, gas fire, sparkles, candles ...) in rooms where Medical Oxygen is used, as it increases the risk of fire.
- Do not smoke nor use e-cigarette all along your treatment with oxygen.

- Do not use toasters, hairdryers, or similar electrical equipment during your treatment with oxygen.
- Do not apply greasy substances (e.g. oils, creams, ointments) on surfaces in contact with oxygen. Only water-based products should be used on the hands and face or inside the nose while using oxygen.
- The pressure regulator must be opened slowly and cautiously to avoid the risk of flash fire.

Thermal burns have occurred related to accidental fire in presence of oxygen.

#### **Advice to caretakers:**

- Handle carefully the cylinder. Ensure that the gas cylinder is not dropped or exposed to knocks.
- Equipment damage may cause obstruction of the outlet and/or wrong information displayed on the manometer with regards to remaining oxygen content and flow delivery leading to insufficient or lack of oxygen administration.

#### **Children**

In pre-term and new-born infants, oxygen therapy may lead to eye damage (retinopathy of prematurity). The doctor will determine the appropriate oxygen concentration to be administered to insure the optimal treatment for your baby.

#### **Other medicines and Medical Oxygen**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

If you are taking or have been prescribed bleomycin (to treat cancer), amiodarone (to treat heart disease), nitrofurantoin (to treat infection), please advise your doctor prior to using oxygen, as there is a possibility of toxic effects to the lungs.

Previous pulmonary damage caused by the pesticide Paraquat may be exacerbated by oxygen. In case of Paraquat intoxication, oxygen supplementation should be avoided as far as possible.

#### **Pregnancy and breast-feeding**

Medical Oxygen can be used during pregnancy but when it is needed only.

Medical Oxygen can be used during the period of breast-feeding.

In all situations, you should inform your doctor if you are pregnant or suspect you might be pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines**

You may drive and use machines when using Medical Oxygen provided your doctor considers that you are both fit and capable.

## **3. How to use Medical Oxygen**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Medical Oxygen will be administered via inhalation and you will be given a facemask, mouthpiece or nasal cannula (prongs) to use which are connected to Medical Oxygen via a suitable medical device. The device must be operated in the manner described by the manufacturer. The amount of oxygen you will receive is controlled by the type of equipment you are supplied with and the flow rate. You should use the flow rate prescribed by your doctor and the equipment provided.

The flow rate of oxygen used in your treatment will depend on the condition it is being used to treat. Your doctor will tell you how much oxygen you should use per day and how long your treatment will be. Medical Oxygen is likely to last.

Other systems used to administer oxygen include face tents, headboxes, cot hoods, a positive pressure mask or supply to a tracheostomy. These systems will only be used to give you oxygen under the direct supervision of attendant and suitably trained medical personnel.

During use the cylinder should be kept upright, away from heat in a well-ventilated area.

Connections for hoses, valves etc. must be kept clean and dry. If necessary, clean only with plain water. Do not use solvents. Use clean, lint free cloths for cleaning and drying off.

Do not use oil or grease on any oxygen equipment.

#### **If you use more Medical Oxygen than you should**

In vulnerable situations, excessive administration of Medical Oxygen can affect respiratory function and in exceptional cases cause neurological adverse effects which can lead to a loss of consciousness in extreme situations.

Prolonged use of too much Medical Oxygen can cause a breathing-related pain, a dry cough, and even breathlessness. If these signs of overdose occur, always contact your doctor or the nearest hospital.

## 4. Possible side effects

Like all medicines, Medical Oxygen can cause side effects, although not everybody gets them.

Side effects are usually seen with high concentrations and after prolonged treatment:

**Very common (may affect more than 1 in 10 people):**

In newborns exposed to high oxygen concentrations: damage to the eye, which can result in impaired vision.

With hyperbaric treatment: ear pain, myopia, barotrauma (injury caused to body tissues or organs by a change in pressure).

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

With hyperbaric treatment: convulsion.

**Uncommon (may affect up to 1 in 100 people):** lung collapse,

With hyperbaric treatment: rupture of the eardrum.

**Rare (may affect up to 1 in 1,000 people):**

With hyperbaric treatment: breathlessness, abnormally low blood sugar level in diabetic patients.

**Undetermined frequency (frequency cannot be estimated from the available data):** breathing-related pain and dry cough, mucosal dryness, local irritation and inflammation of the mucosa.

With hyperbaric treatment: breathing difficulty, involuntary muscular contraction, vertigo, audition impairment, acute serous otitis, sickness, abnormal behaviour, fear of confined spaces (claustrophobia), decrease in peripheral vision, visual changes, clouding of the lens (cataract).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Medical Oxygen

Check the date given on the batch label attached to the cylinder. Do not use Medical Oxygen after the expiry date given on the label.

Medical Oxygen is supplied in cylinders as a gas

- Keep this medicine out of the sight and reach of children
- Medical Oxygen cylinders must be stored away from extremes of temperature
- Medical Oxygen must be stored securely in a well-ventilated place, under cover and kept clean and dry.
- Medical Oxygen must be stored separately from other medical gases and non-medical gases.
- Full cylinders should be stored separately from empty cylinders
- Cylinders up to 5 litres in size should be stored horizontally, larger cylinders should be stored vertically.
- Cylinders should be used in strict rotation so that cylinders with the earliest expiry dates are used first.

## 6. Contents of the pack and other information

**What Medical Oxygen contains**

The name of your medicine is Medical Oxygen commonly known as Oxygen Inhalation Gas

The active substance is Oxygen Ph Eur (minimum purity 99.5%v/v)

**What Medical Oxygen looks like and contents of the pack**

Medical Oxygen is supplied as a gas in a cylinder under pressure. The colour scheme for Medical Oxygen is changing from a black body with a white top to an all-white cylinder. Your cylinder may be of either colour scheme. The cylinder label gives the amount of oxygen provided by the cylinder when it is used at normal atmospheric pressure. Always read the label.

Further information on handling and using medical Oxygen is available from Air Liquide Healthcare Ireland Limited

**Marketing Authorisation Holder and Manufacturer**

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