

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

Other medicines and Medical Oxygen

Tell your doctor or pharmacist if:

- you are taking or have recently taken **amiodarone** (used to treat irregular heartbeat) or **bleomycin** (given as an injection or drip to treat some types of cancer)
- you have Chronic Obstructive Pulmonary Disease (COPD), (a collection of lung diseases caused by damage to the lungs)

Take special care with Medical Oxygen

Care is needed in the handling and use of medical oxygen gas cylinders.

Fire Risks

- Do not smoke or allow those near you to smoke during treatment with Medical Oxygen, smoking during oxygen treatment has caused serious injuries and can prove fatal
- Do not allow naked flames in the area where you are using your Medical Oxygen, since even the smallest spark can cause violent ignition, electrical equipment capable of sparking (including toys which may produce sparks) must not be used where you are using your Medical Oxygen.

Medical Risks

- If oxygen is being used for premature or new-born infant, they must receive a carefully monitored dose of oxygen. Giving too much oxygen can damage their sight.
- If you have a chronic obstructive airway disease you should only receive a carefully monitored dose of oxygen.
- Although Medical Oxygen is necessary for patients having lung damage due to poisons such as paraquat (a type of weed killer), it may worsen the lung injury, the dose must be monitored carefully.
- A slowing down in your breathing caused by drinking alcohol may be made worse by the use of Medical Oxygen.
- Do not breathe medical oxygen at pressures higher than atmospheric.

Special Circumstances

Pregnancy, breastfeeding and fertility.

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

Premature/New-Born Babies

Medical Oxygen for premature or new-born babies should only be taken under the direction of a qualified medical person.

Driving and using machines

Non-continuous use of Medical Oxygen at atmospheric pressure will not affect your ability to drive or operate machinery, however, if you are using oxygen continuously you must be assessed by your doctor.

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 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:

If you may have used more Medical Oxygen than you should, talk to a doctor or pharmacist as soon as possible. However it is very unlikely that an over dose will occur.

Using 100% Medical Oxygen continuously for more than a day may produce chest pain and difficulties in breathing. Such a concentration is likely only to be achieved using specialised (hospital) equipment.

Using Medical Oxygen at pressures higher than atmospheric may lead to convulsions this is only likely to occur in specialised circumstances when using specialised (hospital) equipment such as a hyperbaric chamber.

4. Possible side effects

Like all medicines, Medical Oxygen can have side effects, although not everybody gets them. The toxicity of Medical Oxygen depends upon both the pressure (concentration) of Medical Oxygen that is breathed in and the amount of time that is used for. The higher the pressure that Medical Oxygen is breathed in at, the shorter the time that it can be used safely for.

Side effects may include:

- giving too much oxygen to new-born and premature infants can damage their sight and may be associated other damage these conditions have more than one cause and can occur even in the absence of oxygen therapy
- lung damage from prolonged giving of too much oxygen – symptoms include shortness of breath, cough and chest discomfort
- central nervous system toxicity, if Medical Oxygen is breathed in at pressures of twice atmosphere or more, as in hyperbaric oxygen therapy. This would normally only occur using specialist hospital equipment. Symptoms could include nausea, mood changes, vertigo, twitching, convulsions and loss of consciousness

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.hpra.ie. 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 Industrial Pressure Testing Limited

Marketing Authorisation Holder and Manufacturer

Industrial Pressure Testing Ltd, Unit H5 Marina Commercial Park, Centre Park Road, Cork, Ireland.

This leaflet was last revised in {month YYYY}.