

Patient Information Leaflet

Medical Oxygen. Inhalation Gas. Minimum Purity 99.5 % v/v

Read all of this leaflet carefully because it contains important information for you. Keep this leaflet, you may need to read it again. Ask your pharmacist or doctor if you need more information.

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1. What is Medical Oxygen 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 flow of gas. A variety of cylinders sizes are available.

What Medical Oxygen is used for?

Medical Oxygen is used to increase the 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 diseases 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 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), cystic fibrosis (an inherited disease that affects the lungs), anaerobic infections (infections where lack of oxygen is an important factor) 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 medical emergency
- when the oxygen carrying ability 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 that 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 or as a diluent for anaesthetic gases or vapours

2. Before you use Medical Oxygen

Warnings and Precautions with Medical Oxygen

Care is needed in the handling and use of Medical Oxygen – You must follow your Doctor's instructions.

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 a premature or newborn 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/ Chronic Obstructive Pulmonary Disease (COAD/COPD - a collection of lung diseases caused by damage to the lungs) you must receive a carefully monitored dose of oxygen
- although Medical Oxygen is necessary for patients with lung damage due to poisons such as paraquat (a type of weedkiller), it may worsen the lung injury; the dose must be monitored carefully
- do not breathe Medical Oxygen at pressures higher than atmospheric pressure

Interactions with other medicines, medical conditions or diseases

Interactions with other medicines are unlikely when used as directed. However, it is important that you tell your doctor if you are taking, or have recently taken, any other medicine – even those not prescribed. Unless specially advised by your doctor to do so, do not use Medical Oxygen 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 a Chronic Obstructive Pulmonary Disease (COPD) (a collection of lung diseases caused by damage to the lungs)

Taking Alcohol and Other Risks:

- 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 pressure

Special Circumstances:

Pregnancy

Medical Oxygen can be used if you are pregnant, however, seek medical advice before taking any medicine.

Premature/Newborn Babies

Medical oxygen for premature or newborn babies should only be taken under direction of a qualified medical person.

Breast-feeding

Medical Oxygen can be used if you are breast-feeding, however, seek medical advice before taking any medicine.

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

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 the 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 must use the flow rate prescribed by your doctor and the equipment provided by your supplier.

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 with Medical Oxygen is likely to last.

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

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.

Premature/Newborn Babies

Medical oxygen for premature or newborn babies should only be taken under direction of a qualified medical person.

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 overdose 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 pressure higher than atmospheric may lead to convulsions. This is only likely to occur in specialised circumstances when using decompression units, high altitude mountaineering or diving.

Withdrawal

There are no additional side-effects from withdrawal of oxygen.

4. Possible side effects

Like all medicines Medical Oxygen can have side effects. The toxicity of Medical Oxygen depends upon both the pressure (concentration) of Medical Oxygen that is breathed in and the amount of time that it is used for. The higher the pressure that Medical Oxygen is breathed in at, the shorter the time that it can be safely used for.

Side-effects may include:

- giving too much oxygen in newborn and premature infants can damage their sight and may be associated with other damage (these conditions have more than one cause and can occur even in the absence of oxygen therapy)
- lung damage from prolonged giving 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 atmospheric pressure or more as in hyperbaric oxygen therapy. This would normally only occur in specialist hospital treatment. 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.

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 should be stored securely in a well-ventilated place, under cover and kept clean and dry.
- Cylinders should be stored where they will not be exposed to extremes of temperature.
- Cylinders should be stored at temperatures below 50 °C, they should preferably be stored between 10°C and 30 °C.
- Full cylinders should be stored separately from empty cylinders.
- Medical oxygen cylinders should be stored separately from non-medical cylinders and from other medical cylinders containing different gases.
- Cylinders up to 5 litres in size should be stored horizontally; larger cylinders should be stored vertically.
- Cylinders should be used in strict rotation with the oldest cylinder being used first.
- Keep out of the reach and sight of children

6. Further information

The name of your medicine is **Medical Oxygen**, commonly named as Oxygen Inhalation Gas.

Your medicine is a colourless, odourless gas.

The active substance is Oxygen Ph. Eur., Minimum Purity 99.5% v/v.

Contents of the containers

Oxygen supplied as gas in cylinders: These contain compressed gas. The cylinder sizes quoted are the amount of oxygen provided by the cylinder, when it is used at normal atmospheric pressure.

201, 401 and 2122 litres.

Further information on handling and using medical oxygen is available from your Air Products engineer, who delivers your oxygen or your patient information pack.

The Marketing Authorisation Holder and Manufacturer is:

Air Products Ireland Ltd at Unit 950, Western Industrial Estate, Killeen Road, Dublin 12

Oxygen supplied as: Gas in cylinders Marketing Authorisation No. PA 1075/1/1