

Medical Liquid Oxygen Issue 3

Read all of this leaflet in conjunction with any other safety guidance carefully before you start to use this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your Healthcare Professional.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- This leaflet should be read in conjunction with the safety information provided by Air Liquide.

In this leaflet:

1. What is Medical Liquid Oxygen is and what it is used for.
2. What you need to know before you use Medical Liquid Oxygen.
3. How to use Medical Liquid Oxygen.
4. Possible side effects.
5. How to store Medical Liquid Oxygen.
6. Further Information.

The name of your medicine is Medical Liquid Oxygen. Medical Liquid Oxygen is supplied as a pure gas containing only oxygen. It does not contain any other ingredients.

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

Medical Liquid Oxygen is an inhalation gas (a gas that is breathed in). It is colourless, odourless and tasteless. It is supplied as a liquid gas (at very low temperatures) in a cryogenic vessel.

Oxygen is essential for life. Oxygen breathed in with air goes into your lungs where it is taken into your blood. The blood carries the oxygen to all your body tissues. The tissues take the oxygen from the blood so that they can work properly.

If, for any reason, you are not getting enough oxygen into your blood from your lungs you may be prescribed Medical Liquid Oxygen to breathe to increase the level of oxygen in your body tissues. You will be able to breathe more easily.

Medical Liquid Oxygen is prescribed when you are not getting enough oxygen into your body through the lungs due to lung disease or damage or when you have breathing difficulties.

Medical Liquid Oxygen may also be prescribed/used:

- For your baby if born prematurely or having breathing problems.
- In the treatment of cluster headaches and other conditions where localised blood supply is poor.
- With anaesthetics during surgery and for artificial ventilation in intensive care after surgery or following an accident.
- As a propellant for inhaling other medicines in nebuliser treatment.
- In pressure chambers to reduce the risk of damage as a result of gas bubbles in the blood vessels or if there is gas trapped in body spaces. When the oxygen carrying ability of the blood is reduced, such as in the case of severe carbon monoxide poisoning. It may also be used as part of the treatment of gas gangrene (damage to soft tissue cause by bacterial infection).

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

Do not smoke or allow those near you to smoke during treatment with Medical Liquid Oxygen. (This includes E-cigarettes) as Oxygen helps things burn. Oxygen can cling to fabrics. Smoking during oxygen treatment has proved fatal (due to fire and burns) to more than one patient.

Do not allow naked flames or sources of ignition near you when you are using your Medical Liquid Oxygen.

Read all of the safety advice and guidance provided to you by Air Liquide.

Do not use Medical Liquid 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 Healthcare Professional know.

Warnings and precautions

Talk to your Healthcare Professional before using Medical Liquid Oxygen.

Before you 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 Healthcare Professional 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 Healthcare Professional 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 oxidizing product and promotes combustion. There must be no smoking or open flames (e.g. pilot lights, cookers, oven, gas fire, sparks, candles etc) in rooms where Medical Liquid Oxygen is used, as it increases the risk of fire.
- Do not smoke nor use e-cigarette at all when using Medical Liquid Oxygen.
- Do not use toasters, hairdryers, or similar electrical equipment whilst using Medical Liquid Oxygen.
- Do not apply greasy substances (e.g. oils, creams, ointments) on surfaces in contact with Medical Liquid Oxygen. Only water-based products should be used on the hands and face or inside the nose while using Medical Liquid 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 the 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.
- Oxygen becomes a fluid at approximately -183°C. There is a risk of burns at such low temperatures. Always wear gloves and protective goggles when working with Medical Liquid Oxygen..

Children

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

Other medicines and Medical Liquid Oxygen

Tell your Healthcare Professional 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 healthcare professional 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 Liquid Oxygen can be used during pregnancy.

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

In all situations, you should inform your Healthcare Professional 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 healthcare professional for advice before taking any medicine.

Driving and using machines

You may drive and use machines when using Medical Oxygen providing that your Healthcare Professional considers that you are both fit and capable.

3. How to use Medical Liquid Oxygen

Always follow the instructions given to you by your Healthcare Professional. Do not stop treatment or change your treatment without consulting your Healthcare Professional first.

You will normally use Medical Liquid Oxygen by breathing the gas in through nasal prongs or through a mask. The nasal prongs or mask are connected to the Medical Liquid Oxygen via specialised equipment that you will be supplied with. The equipment must be operated in the manner described by the manufacturer. Take extra care as the parts will become frosted when filling the portable system from the base unit. This can cause cold burns.

All equipment used with the Medical Liquid Oxygen should be kept clean and dry. Do not use oil or grease on any equipment that is used with Medical Liquid Oxygen.

Do not attempt to repair any equipment supplied to you for use with Medical Liquid Oxygen, contact Air Liquide to arrange the repair of any faulty equipment.

In vulnerable situations, excessive administration of Medical Liquid 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 Liquid Oxygen can cause a breathing-related pain, a dry cough, and even breathlessness. If these signs of overdose occur, always contact your healthcare professional or the nearest hospital.

4. Possible side effects

Like all medicines Medical Liquid 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.

Unknown 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, decrease in peripheral vision, visual changes, clouding of the lens (cataract).

Contact with Medical Liquid Oxygen causes frostbites.

Reporting of side effects:

If you get any side effects, talk to your Healthcare Professional. 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. Storage of Medical Liquid Oxygen

- Keep Medical Liquid Oxygen out of the reach and sight of children.
- Do not smoke where Medical Liquid Oxygen is stored (this includes E-cigarettes).

Medical Liquid Oxygen containers should be stored:

- Away from open flame, heat and sources of ignition
- In a well ventilated place,
- Under cover
- Kept clean and dry.
- Where they will not be exposed to extremes of temperature.

All equipment should be returned to Air Liquide.

For further advice on storage please refer to the literature provided by Air Liquide.

Use by date

Do not use Medical Liquid Oxygen after the expiry date on the label.

6. Further Information

Contents of the containers

Medical Liquid Oxygen 100% inhalation gas is supplied as a liquid gas (at very low temperatures) in a cryogenic vessel.

The Marketing Authorisation Holder for Medical Liquid Oxygen is Air Liquide Limited, Station Road, Coleshill, Birmingham, West Midlands, B46 1JY.

Medical Liquid Oxygen is manufactured by Air Liquide in the UK.

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Contact:

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Air Liquide Healthcare is a world leader in medical gases, home healthcare, hygiene products and healthcare specialty ingredients. It aims to provide customers in the continuum of care from hospital to home with medical products, specialty ingredients and services that contribute to protecting vulnerable lives.