



Medical Gas Data Sheet (MGDS)

Medical oxygen (liquid)

Essential safety information:

Summary of Product Characteristics (SPC) Pages

2 - 6 Additional Safety Information Pages 7 - 8



Medical oxygen (liquid)

SPC

1. Name of the medicinal product	Medical oxygen.
2. Qualitative and quantitative composition	<p>Liquid medical oxygen is supplied to the following specification:</p> <p style="padding-left: 40px;">medical oxygen purity 99.5% (min).</p> <p>The liquid medical oxygen cylinder specification complies with the current European Pharmacopoeia monograph (0417).</p>
3. Pharmaceutical form	Medicinal gas, cryogenic.
4. Clinical particulars	<p>4.1 Therapeutic indications</p> <p>Liquid medical oxygen is widely used in clinical practice to provide a basis for most modern anaesthetic techniques including pre and postoperative management.</p> <p>To restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions such as:</p> <ul style="list-style-type: none"> • cyanosis of recent origin as a result of cardio-pulmonary disease • surgical trauma, chest wounds and rib fracture • shock, severe haemorrhage and coronary occlusion • carbon monoxide poisoning • hyperpyrexia • major trauma, i.e. road traffic accidents and gunshot wounds • in the management of sudden cardiac and respiratory arrest, whether drug induced or traumatic • in the resuscitation of the critically ill, when the circulation is impaired in neo-natal resuscitation. <p>In all cases, the liquid medical oxygen is vaporised to a compressed gas at ambient conditions before being administered to the patient.</p>
4.2 Posology and method of administration	Liquid medical oxygen is administered by vaporising the liquid to a gas at ambient temperatures and delivered for inhalation through the lungs. The major exception is when a metered supply is fed into the oxygenator of an extracorporeal circulation of a cardio-pulmonary by-pass system.
4.3 Contraindications	There are no absolute contraindications to the use of oxygen, but the inspired concentration should be limited in the case of premature infants and those patients with chronic bronchitis and emphysema.
4.4 Special warnings and precautions for use	<p>Special care is needed when liquid oxygen is administered:</p> <ul style="list-style-type: none"> • to neonates where the inspired concentration should not exceed 40% because of the risk of retrolenticular fibroplasia • to elderly chronic bronchitic patients in whom the inspired concentration should only be raised in stages of 1% and probably should not exceed 30% • in hyperbaric chambers in the management of conditions such as carbon monoxide poisoning, anaerobic infections and acute ischaemic disease. Convulsions may occur at 3 bar(g) after a few hours. <p>Oxygen levels should be monitored as required in the breath, blood and tissue to ensure that appropriate concentrations are not exceeded.</p>

Oxygen supports combustion, and smoking should be prohibited when medical oxygen is in use and no naked flames should be allowed.

Care is needed when handling and using liquid medical oxygen.

4.5 Interaction with other medicinal products and other forms of interaction The pharmacokinetic activity of oxygen is modified by changes in blood carbon dioxide tension, but this has little clinical significance.

4.6 Pregnancy and lactation Oxygen does not adversely affect pregnancy and lactation.

4.7 Effects on ability to drive and use machines In normal circumstances, medical oxygen does not interfere with the conscious level but patients who require continuous oxygen support are obviously not fit either to drive or to operate machinery.

4.8 Undesirable effects Medical oxygen toxicity can occur as manifested by:

- retrolental fibroplasia in premature infants exposed to oxygen concentrations greater than 40%
- convulsions appear after a few hours exposure to medical oxygen at pressures above 3 bar(g)
- retrosternal soreness associated with coughing and breathing difficulties, made worse by smoking and exposure to cold air after breathing pure oxygen at atmospheric pressure for several hours.

4.9 Overdose As detailed above in 'Undesirable effects'.

5. Pharmacological properties

5.1 Pharmacodynamic properties Pharmacotherapeutic Group - medical gas.
ATC Code - V03AN01.

The characteristics of medical oxygen are:

odourless, colourless gas	
molecular weight	32.00
boiling point	-183.1°C (at 1 bar)
density	1.335 kg/m ³ (at 15°C).

Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

The basal oxygen consumption in man is about 250ml/min for a body surface of 1.8m². It is reduced by about 10% during anaesthesia and natural sleep and by about 50% for a 10°C fall in body temperature.

Alveolar air contains about 14% oxygen (105mm Hg) and the arterial blood has an oxygen tension of 97mm Hg.

The difference, known as the alveolar-arterial oxygen tension gradient, increases with age. The difference may be as great as 30mm Hg in a healthy, elderly individual.

Oxygen in the blood is mostly combined with haemoglobin. 1.34ml per 9ml to give a maximum capacity of 20ml per 100ml of blood. A small amount, 0.3ml, exists in solution in the same volume of blood.

The concept of oxygen availability first described by Richards in 1943 and later elaborated by Freeman and Nunn, has been used to quantify the amount available to the body.

It can be expressed as the product of the cardiac output and the oxygen content of the blood.

Available oxygen is calculated by:

$$\text{(cardiac output) } \times \text{Hb concentration} \times 1.34 \times (\% \text{ saturation}).$$

Substituting the normal values for available oxygen the amount is:

$$\text{available oxygen: } ((5000\text{ml}) \frac{15}{100} \times 1.34 \times \frac{95}{100}) = 950\text{ml.}$$

The average healthy individual with a basal oxygen consumption has no more than four minutes supply of oxygen in the blood.

5.2 Pharmacokinetic properties The uptake of medical oxygen by the blood in the lungs and discharge to the tissues is determined by the oxygen dissociation curve.

The characteristic sigmoid shape ensures that, at tensions between 40 and 15mm Hg, the oxygen carried in the blood from the lungs can be readily given up to the tissues.

The uptake from the lungs is rapid, because blood flow through the capillaries, where exchange takes place, occurs in about 0.5 seconds. The uptake of oxygen is favoured by the simultaneous loss of carbon dioxide which is then excreted in the expired air. Conversely the entry of carbon dioxide into blood from the tissues facilitates oxygen transfer to the cells.

At rest, mixed venous blood returning to the lungs contains 13-14ml of oxygen per 100ml, but with severe exercise, the oxygen content may fall to 3-4ml. In very active tissue, almost complete extraction occurs.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

None.

6.2 Incompatibilities

Liquid medical oxygen is non-flammable but strongly supports combustion (including some materials that do not normally burn in air). It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.

6.3 Shelf life

6 months.

6.4 Special precautions for storage

Liquid medical oxygen cylinders should be:

- stored upright under cover, preferably inside in a well ventilated area, kept dry and clean and not subjected to extremes of heat and away from stocks of combustible material
- stored separately from industrial and other non-medical cylinders
- stored to maintain separation between full and empty cylinders
- used in strict rotation so that cylinders with the earliest filling date are used first
- stored separately from other medical cylinders within the store.

Liquid medical oxygen bulk storage tanks should be sited at least 3 metres from boilers and other sources of naked lights, fuel stores, paint stores and other volatile flammable materials.

Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the emergency services should be advised of the location of the cylinder stores and bulk stores.

Care is needed when handling and using liquid medical oxygen cylinders.

6.5 Nature and contents of container

Bulk liquid medical oxygen storage tanks are constructed as a double skin vacuum insulated vessel with the interspace between the inner and outer vessel filled with an inorganic insulant to prevent any heat inleak. The inner vessel is constructed of stainless steel or aluminium. The vessels are fitted with brass valves and copper interconnecting pipework.

The customer storage tanks should be installed to the specifications detailed in HTM 02.

The portable liquid cylinders used for supplying liquid medical oxygen are manufactured in stainless steel, with stainless steel valves and components.

The portable liquid cylinders are fitted with an internal vaporisation coil in the interspace, to convert the liquid oxygen to gas, for use by the patient. The liquid cylinders have an operating pressure of up to 12.1 bar (g) and a capability of supplying vaporised gas at a rate of up to 300 litres/min for each cylinder.

The bulk storage vessels have an external ambient heated vaporiser fitted to ensure that only gas is supplied down the pipeline to the ward outlet points. The bulk storage vessels (VIE) have an operating pressure of up to 16 bar (g). The outlet flow capability depends upon the size of the vessel and the type of vaporiser system.

The valves are constructed from either high tensile brass or stainless steel. The regulator diaphragm and relief valve components, used to control the flow and pressure of the gas, are made from oxygen compatible materials.

All materials used in the construction of the tanks and valves are compatible with liquid oxygen in terms of reacting or suitability with respect to auto ignition.

Liquid cylinder and valve details

Cylinder size	Gas content (litres)	Cylinder construction	Valve outlet	Valve construction
DLC1	1,032	Stainless steel vacuum insulated	Product specific filling connector Fir Tree outlet	Stainless steel
DLC 30	28,800	Stainless steel vacuum insulated	Product specific filling connector Fir Tree outlet	Stainless steel
DLC 37	31,820	Stainless steel vacuum insulated	Product specific filling connector Fir Tree outlet	Stainless steel
DLC 200	148,000	Stainless steel vacuum insulated	Product specific filling product specific outlet	Stainless steel

6.6 Special precautions for disposal (and other handling)

All personnel handling liquid oxygen cylinders should have adequate knowledge of:

- properties of the gas
- correct operating procedures for the liquid oxygen cylinder
- precautions and actions to be taken in the event of an emergency.

Use of cylinders

When liquid medical oxygen cylinders are in use ensure that they are:

- only used for medicinal purposes
- kept upright at all times
- turned off, when not in use, using only moderate force to close the valve
- only moved with the appropriate size and type of trolley or handling device
- handled with care and not knocked violently or allowed to fall
- firmly secured to a suitable cylinder support when in use
- not allowed to have any markings, labels or batch labels obscured or removed not used in the vicinity of persons smoking or near naked lights.

After use

When the liquid medical oxygen cylinder is empty ensure that the:

- outlet valves are closed using moderate force only
- empty liquid cylinders are immediately returned to an empty cylinder storage area for return to POL.

General

Hazards to health arise from intense cold or displacement of air by rapidly evaporating liquid and extreme care is needed when handling liquid medical oxygen.

Transient exposure to very cold gas can provoke attacks of asthma in susceptible subjects and prolonged breathing of cold gas may damage lung tissue.

Due to the low temperature of liquid medical oxygen (below -183°C at atmospheric pressures), the liquid, or even cold gases, can cause damage to the skin when directly in contact. Unprotected parts of the skin coming into direct contact with uninsulated items of cold equipment may also stick to the flesh and may be torn on removal.

It is recommended that non-absorbant leather gloves and goggles should be worn when handling liquid medical oxygen.

7. Marketing authorisation holder

Pakistan Oxygen Limited (Previously Linde Pakistan Limited)
PO Box # 4845, Dockyard Road, West Wharf Karachi-74000, Pakistan.

8. Marketing authorisation number(s)

PL 0735/0009.

9. Date of first authorisation/renewal of the authorisation

Date first granted: 01/09/1972.
Date of renewal: 21/07/1992.

10. Date of revision of the text

Not applicable.

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Medical oxygen (liquid)

Additional Safety Information

Pakistan Oxygen Limited
PO Box # 4845, Dockyard Road, West Wharf Karachi-74000,
Pakistan.

2. Hazards

Classification labelling and packaging regulations



Danger.

May cause or intensify fire; oxidiser (H270).
Contains gas under pressure; may explode if heated (H280).

Keep/Store away from clothing, hydrocarbons and combustible materials (P220).
Keep reduction valves free from grease and oil (P244).
In case of fire: stop leak if safe to do so (P370 + P376).
Protect from sunlight: store in a well-ventilated place (P410 + P403).

Dangerous Substances Directive



Contact with combustible material may cause fire (R8).
Keep out of the reach of children (S2).
Keep away from combustible material (S17).

Additional safety statements

Contact with combustible material may cause fire.
No smoking or naked flames near medical oxygen cylinders.
Refrigerated liquefied gas. Contact with product may cause cold burns or frost bite.
Liquid medical oxygen may cause cold burns if the liquid comes into contact with exposed skin. Always wear suitable protective equipment when handling vessels.
Use no oil or grease.
Use cylinder upright.
Keep away from extremes of heat and combustible material.
Store vessels under cover in a clean, dry and well ventilated area.

Liquid medical oxygen is a refrigerated liquified gas which may cause cold burns or frostbite if it comes into contact with unprotected skin.

Liquid medical oxygen is a non-flammable gas but is a very strong oxidant. It will strongly support and intensify combustion. It may react violently with combustible materials such as oils and grease.

3. Fire fighting measures

If liquid medical oxygen vessels are involved in a fire:

- if it is safe to do so,
- close supply valve to stop the flow of product
- if it is not safe,
- cool with water from a protected position.

All types of fire extinguishers may be used when dealing with a fire involving liquid medical oxygen cylinders.

No special protective equipment for fire fighters is required. There are no hazardous combustion products released from the gas.

4. Accidental release measures If a large volume of liquid medical oxygen is released, if safe to do so, you should:

- close supply valve
- where possible, eliminate all sources of ignition.

Prevent the product from entering sewers, basements and workpits, or any place where its accumulation can be dangerous.

If the release continues, evacuate the area and ensure that the affected area is adequately ventilated and any spilled liquid has evaporated before re-entry.

Complete evaporation of liquid will be observable by the ground being free from frost.

Self-contained breathing apparatus is not required to be used if liquid medical oxygen is released in a confined area.

5. Exposure controls When using liquid medical oxygen ensure adequate ventilation.

If clothing becomes impregnated with oxygen (due to a leak), keep away from sources of ignition or open flames.

Clothing impregnated with oxygen should be ventilated in fresh air for a minimum of 15 minutes.

Protect eyes, face and skin from liquid splashes from the liquid oxygen by wearing protective clothing and gloves.

If liquid medical oxygen makes contact with the eye, flush thoroughly with water for at least 15 minutes.

If liquid medical oxygen comes into contact with the skin, frostbite may occur, due to the extremely cold temperature of the product. To treat frostbite, spray damaged skin area with water for at least 15 minutes and apply a sterile dressing. Obtain medical assistance in both instances.

6. Disposal considerations Any venting of liquid medical oxygen should only be carried out by a suitable authorised and trained person.