

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Liquid Oxygen.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The Liquid Medical Oxygen is supplied to the following specification:
Medical Oxygen Purity 99.5% (min)

The Liquid Medical Oxygen specification complies with the current European monograph (0417)

3 PHARMACEUTICAL FORM

Medicinal gas, liquefied.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Oxygen is widely used:

In clinical practice to provide a basis for virtually all modern anaesthetic techniques as well as pre and post operative management.

To restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions such as:

- cyanosis of recent origin as a result of cardio-pulmonary disease
- surgical trauma, chest wounds and rib fractures
- shock, severe haemorrhage and coronary occlusion
- carbon monoxide poisoning
- major trauma, e.g. road traffic accidents and gunshot wounds
- hyperpyrexia
- 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.

4.2 Posology and method of administration

There is no distinction generally between the use of oxygen in age groups other than neonates (see below).

The fundamental indication is the presence of hypoxia due to whatever cause.

Modern oxygen usage requires separate devices for administering the gas in high and in low concentrations. The lowest concentration should not fall below that present in ambient air (20.9%).

These devices have been classified as follows:

Fixed Performance Systems (patient independent)

High flow – venti masks

Low flow – anaesthetic circuits

In all these systems the oxygen concentration is pre-determined by the clinician

Variable Performance Systems (patient dependent)

without re-breathing-catheters and cannulae

with re-breathing through a face mask such as the MC Edinburgh and Pneumask.

These systems only function by means of the patient who creates the inspired mixture by the act of breathing. Various patient and device factors influence the result.

Special Care is needed when oxygen is administered:

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 initially be 24% and only 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 ischemic disease.

Convulsions and other central nervous system (CNS) effects may occur at 2 atmospheres or more, after a few hours exposure to pure oxygen. At higher pressures more rapid onset of CNS symptoms will occur.

Careful monitoring is required, but modern methods of measuring oxygen in breath, blood and tissues have made this relatively simple.

Almost invariably, oxygen is administered through the lungs by inhalation.

The major exception is when a metered supply is fed into the oxygenator of the extracorporeal circulation of a cardio-pulmonary by-pass system.

4.3 Contraindications

There are no absolute contra-indications in 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

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

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

Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of additional oxygen should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

The pharmacokinetic activity of oxygen is modified by changes in the blood carbon dioxide tension, but this has little clinical significance.

The use of higher levels of oxygen can increase the risk of pulmonary toxicity in patients who have been administered Bleomycin, Amiodarone and Nitrofurantoin or similar antibiotics. In these cases oxygen should be administered with caution and at levels kept as low as possible.

4.6 Fertility, pregnancy and lactation

Oxygen does not adversely affect pregnancy and lactation.

4.7 Effects on ability to drive and use machines

In normal circumstances, oxygen does not interfere with the conscious level but patients who require continuous oxygen support will require individual assessment as to their ability to drive or to operate machinery.

4.8 Undesirable effects

Oxygen toxicity can occur as manifested by:

retrolenticular fibroplasia in premature infants exposed to oxygen concentrations greater than 40%.
central nervous systems toxicity including dizziness, convulsions and loss of consciousness after only 2-3 hours of exposure to pure oxygen at 2 or more atmospheres, e.g. sports and deep sea diving.
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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

As detailed in 4.8. above.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group - Medical Gas

ATC Code: V03AN01

The characteristics of oxygen are:

- Odourless, colourless gas.
- Molecular weight 32.00
- Boiling point -183.1°C (at 1 bar)
- Density 1.335kg/M3 (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 1.8sq metres. 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 15% oxygen at 14kpa (105mm Hg) and the arterial blood has an oxygen tension of 13kpa (97mm Hg). The difference known as the alveolar-arterial oxygen tension gradient, increases with age. The difference may be as great as 4kpa (30 mm Hg) in a healthy, elderly individual.

Oxygen in the blood is mostly combined with haemoglobin. Normally haemoglobin in arterial blood is 97% saturated and the oxygen content of the blood is 19.8 vol%, 0.3ml of this being carried in solution. The remainder is held in chemical combination with haemoglobin.

The concept of oxygen availability can be expressed as the product of the cardiac output and the oxygen content of the blood.

The average healthy individual with a basal oxygen consumption has no more than 4 minutes supply of oxygen in the blood.

5.2 Pharmacokinetic properties

The uptake of 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 5kpa (40mm Hg) and 2 kpa (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 the 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

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

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Medical Liquid 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

Medical Liquid 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 bulk storage area. Emergency Services should be advised of the location of the cylinder stores and bulk stores.

Care is needed when handling and using Medical Liquid Oxygen cylinders.

6.5 Nature and contents of container

Bulk Medical Liquid 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 Medical Liquid Oxygen are manufactured in stainless steel, with stainless steel valves and components

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.

The portable liquid cylinders are fitted with an internal vapoursation 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.

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
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 Connector Fir Tree Outlet	Stainless Steel

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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 Medical Liquid 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 Medical Liquid Oxygen cylinders are 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 BOC.

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 Medical Liquid Oxygen (below -183OC 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 tom on removal.

It is recommended that non-absorbent leather gloves and goggles should be worn when handling Medical Liquid Oxygen.

7 MARKETING AUTHORISATION HOLDER

BOC Gases Ireland Limited
J F Kennedy Drive
Bluebell
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA0208/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

October 2015

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable