

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Liquid Oxygen.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The Medical Liquid Oxygen is supplied as a medical gas as a refrigerated liquid gas. It is either supplied as a bulk medical gas by transfer from a vacuum insulated mobile tanker or as a liquid in portable liquid cylinders.

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

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

3 PHARMACEUTICAL FORM

Medicinal gas, cryogenic.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Medical Liquid 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.

In all cases, the Medical Liquid Oxygen is vaporised to a compressed gas at ambient conditions before being administered to the patient

4.2 Posology and method of administration

There is no distinction generally between the use of oxygen in age groups other than neonates (see section 4.4).

Medical Liquid 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 the extracorporeal circulation of a cardio-pulmonary by-pass system.

Refer to section 6.6 for instructions on how to use the Medical Liquid Oxygen homecare storage vessel for filling portable cylinders.

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

Special Care is needed when oxygen is administered:

- to neonates where the inspired concentration should not exceed 40% because of the risk of retro lenticular fibroplasia.
- to elderly chronic bronchitis 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 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

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

Oxygen levels should be monitored as required in the breath, blood and tissue to ensure that appropriate concentrations are not exceeded.

Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of gases containing more than 21% oxygen should be avoided.

Medical Liquid Oxygen is non-flammable but strongly supports combustion and should not be used near sources of ignition.

Smoking should be prohibited when using Medical Liquid Oxygen.

Under no circumstances should oils or grease be used to lubricate any part of the Medical Liquid Oxygen storage vessel or the associated equipment used to deliver the gas to the patient.

Where moisturising creams are required for use with a facemask or in nasal passages oil based creams should not be used.

Check that hands are clean and free from any oils or grease.

Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling Medical Liquid Oxygen vessels or equipment.

Care is needed when handling and using Medical Liquid Oxygen vessels. Always use vessels upright unless otherwise instructed.

Medical Liquid Oxygen is a cryogenic liquid with a temperature of -183°C at ambient pressure. The medical oxygen generated by vapourising the Medical Liquid Oxygen will also be very cold and should be warmed to ambient temperature using appropriate equipment prior to administration to the patient.

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

Never directly touch any of the cold parts of the vessel or associated equipment or allow liquid oxygen to come into contact with your skin as this could cause a cold burn.

If this occurs immerse affected skin in tepid water and seek medical treatment.

Use appropriate Personal Protective Equipment (PPE) and follow the medical equipment instructions for use when using or handling Medical Liquid Oxygen.

Clothing and materials may become saturated with oxygen if it is exposed to a Medical Liquid Oxygen leak or an excessive gas release from the Medical Liquid Oxygen vessel.

If clothing becomes saturated the wearer should be advised to walk around in a well ventilated area for at least 15 minutes, keeping well away from naked flames or sources of ignition.

Ensure that the Medical Liquid Oxygen vessel is stored in a well ventilated area so that any leak of liquid or gas will naturally disperse over time.

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:

- preferably stored inside, 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 gas containers.
- stored to maintain separation between full and empty vessels.
- used in strict rotation so that vessels with the earliest filling date are used first.
- stored separately from other medical cylinders within the store
- stored in a secure and upright position to avoid spilling of the liquid
- stored in a well ventilated area
- stored without a cover or material over the vessel

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 vessel storage area and the Emergency Services should be advised of the location of the vessel store.

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

6.5 Nature and contents of container

Medical Liquid Oxygen is stored either in a static vacuum insulated storage vessel or supplied in a portable cryogenic liquid vessel for homecare use. The Medical Liquid Oxygen storage vessels supplied to healthcare facilities (referred to as Vacuum Insulated Evaporators (VIE)) as the supply source to a medical gas pipeline system are sized as per the recommendations detailed in the NHS Estates Guidance Document HTM 02. The cryogenic storage vessels have a stainless steel or aluminum inner vessel that is contained within a mild steel outer vessel. The interspace between the two vessels is insulated and maintained at a vacuum to maintain the Medical Liquid Oxygen as a cryogenic liquid with minimal losses. The vessels are fitted with brass valves and copper interconnecting pipework. The bulk storage vessels have an external ambient heated vaporiser to allow the Medical Liquid Oxygen to be vaporized and heated to ambient temperature prior to begin supplied to the pipeline system for distribution throughout the healthcare facility. The bulk storage vessels have an operating pressure of up to 16 bar (g) and provide a supply of gas to the pipeline system at approximately 4 bar (g). The outlet flow capability depends upon the size of the vessel and the type of vaporiser system. Medical Liquid Oxygen is supplied to patients at home using Homecare Medical Liquid Oxygen vessels. These are manufactured from stainless steel, with stainless steel valves and components. These vessels are fitted with an internal vaporisation coil in the interspace, to convert the Medical Liquid Oxygen to gaseous Medical Oxygen for patient use. The vessels are also fitted with a flow selector to provide the patient with their prescribed flowrate.

These Homecare Medical Liquid Oxygen vessels are designed to either supply the patient with their prescribed flowrate or to fill Portable Liquid Medical Oxygen cylinders in order to provide the patient with a lightweight ambulatory supply source. The portable cylinders are designed to be refilled by the patient/carer and are compliant with the requirements of BS EN ISO18777. All components used with the Liquid Medical Oxygen vessels supplied to healthcare facilities and Portable Liquid Medical Oxygen cylinders for homecare use are compatible with the requirements of BS EN ISO15001.

Liquid Vessel and Valve Details

Homecare Liquid Medical Oxygen Vessels

Vessel Name	Water Content (litres)	Nominal Gas Content (litres)	Height (cm)	Diameter (cm)	Full Weight (kg)	Nominal operating pressure (kPa)	Maximum Outlet Flow (L/min)
DLC 30	31.2	25,600	74.9	35.6	54.4	160	15
DLC 31	33.1	24,900	83.8	36.1	56.3	160	10
DLC 37	38.3	31,400	83.2	35.6	64.4	160	15
DLC 41	44.5	33,500	97.8	36.1	71.7	160	10
DLC 45	46.6	38,300	94	35.6	75.7	160	15
DLC 46	46	37,600	95.3	39.1	77.1	152	10

Hospital Vessels

Vessel Name	Gross Water Capacity (litres)	Nominal Medical Oxygen Gas Capacity (M ³)	Diameter (M)	Height (M)
VIE 10	1480	844	1.38	3.35
VIE 17	1885	1350	1.39	3.73
VIE18	2000	1527	1.83	3.85
VIE18	1900	1510	1.60	2.85
VIE23	2475	1890	1.60	3.30
VIE25	2773	2115	1.62	3.89
VIE29	3230	2450	1.90	3.52
VIE30	3160	2530	1.60	4.20
VIE31	3327	2353	1.62	4.27
VIE33	3323	2520	1.52	4.21
VIE42	4500	3497	1.70	4.70
VIE44	4700	3700	1.60	5.32
VIE49	4941	4160	1.90	4.85
VIE53	5490	4430	1.90	4.85
VIE56	6087	4740	1.62	6.77
VIE57	6000	4790	1.60	6.57
VIE58	6204	4920	1.73	4.62
VIE60	6050	5100	1.60	7.20
VIE61	6082	4865	1.52	6.66
VIE75	7900	6300	2.30	4.48
VIE83	9000	6991	1.98	6.55
VIE90	9990	7580	1.90	7.48
VIE95	9990	8010	1.90	7.48
VIE102	14514	8530	2.44	7.54
VIE104	10400	8740	2.30	5.73
VIE105	11350	8820	2.57	4.93

VIE110	11535	9240	2.00	7.50
VIE111	11115	8890	2.50	4.68
VIE127	12065	10100	2.60	5.20
VIE130	14400	10950	2.44	7.32
VIE134	14500	11275	2.40	7.50
VIE151	16198	12700	2.18	7.33
VIE185	19328	15540	2.40	7.10
VIE191	20030	15600	2.57	7.43
VIE193	20400	16200	2.30	9.48
VIE196	19610	15686	2.50	7.18
VIE200	20355	16300	2.40	8.40
VIE201	22300	17405	2.73	8.43
VIE207	22300	20800	2.70	8.30
VIE247	25762	20900	2.18	10.65
VIE248	26150	21900	2.20	11.70
VIE261	27500	22700	2.30	12.30
VIE270	28500	22310	3.10	7.51
VIE281	28105	24200	2.50	10.10
VIE300	30205	24200	2.40	11.60
VIE337	36350	28700	3.88	6.73
VIE341	35488	27680	2.90	9.37
VIE345	34515	32200	3.57	7.07
VIE384	40500	34073	3.10	10.00
VIE405	40500	34460	3.10	10.00
VIE416	43373	33280	2.90	10.95
VIE420	41600	34485	2.60	12.90
VIE432	42835	36900	3.57	8.15
VIE438	46100	40800	2.84	11.70
VIE485	50482	39260	3.05	11.20
VIE490	49020	39260	3.00	11.70
VIE497	52600	42400	3.10	12.50
VIE505	54530	48620	3.88	9.10
VIE570	60000	48000	2.84	14.60
VIE608	60390	49350	3.57	10.64
VIE610	61620	49350	3.00	14.20
DLC200	208	168	0.50	1.80
DLC230	242	194	0.70	1.50
DLC950	1000	801	1.10	2.00
DLC2000	2050	1686	1.40	2.80

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 vessels should have adequate knowledge of:

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

The oxygen can either be supplied directly from the Homecare Medical Liquid Oxygen vessel or from a Portable Medical Liquid Oxygen cylinder that has been filled from a Homecare vessel by the patient/carer.

If using the Homecare Medical Liquid Oxygen vessel directly the following instructions are applicable as to how to prepare the Homecare Medical Liquid Oxygen vessel:

- Check contents gauge of the Homecare Medical Liquid Oxygen vessel to ensure there is enough liquid available
- Attach tubing to the outlet connector
- Open the flow control valve and adjust flowrate to prescribed flow. Check that the gas is flowing
- Check for leaks. If a leak is detected follow the manufacturer's instructions.

If using the Portable Medical Liquid Oxygen cylinder as the supply source plan to fill the portable cylinder just prior to when you need to use it.

The following instructions are applicable as to how to prepare the Homecare Medical Liquid Oxygen vessel in order to fill the portable cylinder:

- Ensure that the connecting faces of the Homecare Medical Liquid Oxygen vessel and the Portable Medical Liquid Oxygen cylinder are clean and free from oil or grease
- Check contents gauge of the Homecare Medical Liquid Oxygen vessel to ensure there is enough liquid available to fill portable cylinder
- Firmly push Portable Medical Liquid Oxygen cylinder onto connector of the Homecare Medical Liquid Oxygen vessel.
- Check for leaks.
- If a leak is detected remove portable cylinder
- Fill portable cylinder following manufacturer's instructions.
- Do not leave the units unattended as the portable Medical Liquid Oxygen cylinder is being filled.
- Remove the portable Medical Liquid Oxygen Cylinder from the Homecare Medical Liquid Oxygen vessel as soon as it has been filled. Do not store portable cylinder in engaged position on vessel

Use Of Vessels

When using liquid vessels:

- Vessel valves and any associated equipment must never be lubricated and must be kept free from oil and grease
- Keep vessels in upright position and clear from obstructions. Overturning could cause spillage of extremely cold liquid/gas
- Liquid vessels should be handled with care and not knocked violently or allowed to fall.
- Liquid vessels should only be moved by trained people
- Do not cover vessels
- Smoking and naked lights must not be allowed within the vicinity of liquid vessels.

After Use

The flow control valve on both the Portable Medical Liquid Oxygen cylinder and Homecare Medical Liquid Oxygen vessel should be closed after use and when the unit is empty

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

April 2018

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable