BOC
A Member of The Linde Group

Liquid medical oxygen.

Essential safety information.

BOC: Living healthcare

Liquid medical oxygen SPC

1. Name of the medicinal product

Liquid medical oxygen.

2. Qualitative and quantitative composition

Liquid medical 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.
Liquid medical oxygen is supplied to the following specification:
medical oxygen purity 99.5% (min).
The liquid medical oxygen cylinder specification complies with the current European Pharmacopoeia monograph (0417).

3. Pharmaceutical form

Medicinal gas, cryogenic.

4. Clinical particulars

4.1 Therapeutic indications

Liquid medical oxygen is widely used

- in clinical practice to provide a basis for most modern anaesthetic techniques including pre and postoperative 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 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.

In all cases, the liquid medical oxygen is vaporised to a compressed gas at ambient conditions before being administered to the patient.

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. The need for medicinal oxygen should be determined by obtaining arterial blood gas values and/or by monitoring SpO_2. The inspired oxygen should be titrated when used for long term oxygen therapy in patients with chronic hypoxic respiratory failure. A SaO_2/SpO_2 between 88 and 92% is commonly assessed as adequate in patients with chronic obstructive pulmonary disease (COPD). A too liberal administration can increase the oxygen SaO_2/SpO_2 clearly above the patient's normal range, which may cause respiratory depression because of chemoreceptor insensitivity for CO_2. Blood gases should be monitored to avoid excessive retention of CO_2 in

patients with hypercapnia or reduced CO_2- sensitivity, in order to adjust the oxygen therapy. Refer to section 6.6 for instructions on how to use the liquid medical oxygen homecare storage vessels for filling portable cylinders.

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

Special care is needed when liquid 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 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.

Oxygen levels should be monitored as required in the breath, blood and tissue to ensure that appropriate concentrations are not exceeded. In patients with reduced sensitivity for carbon dioxide pressure in arterial blood, high concentrations of oxygen may cause, respiratory depression subsequently causing carbon dioxide retention (hypercapnia), which in extreme cases can lead to carbon dioxide narcosis.

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.

Liquid medical oxygen is non flammable but strongly supports combustion and should not be used near sources of ignition. Smoking should be prohibited when using liquid medical 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 liquid medical oxygen vessels or equipment.

Care is needed when handling and using liquid medical oxygen vessels. Always use vessels upright unless otherwise instructed.

Liquid medical oxygen is a cryogenic liquid with a temperature of -183°C at ambient pressure. The medical oxygen generated by vapourising the liquid medical 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 liquid medical oxygen.

Clothing and materials may become saturated with oxygen if it is exposed to a liquid medical oxygen leak or an excessive gas release from the liquid medical 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 liquid medical 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 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 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

Oxygen toxicity can occur as manifested by:

- retrolenticular 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.

The most serious side effects that may occur are severe difficulty in breathing, so called respiratory distress syndrome. Too liberal oxygen administration may also cause respiratory depression in susceptible patients with reduced chemoreceptor sensitivity as seen in e.g. some patients with chronic obstructive pulmonary disease (COPD) causing hypercapnia (frequency not known).

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 The Yellow Card System www.mhra.gov.uk/yellowcard

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
- boiling point -183.1°C (at 1bar(g))
- density 1.355kg/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 1.8m^2. 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 of oxygen 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:
(cardiac output) x Hb concentration x 1.34 x (% saturation).

Substituting the normal values for available oxygen the amount is:
available oxygen: ((5000ml) 15/100 x 1.34 x 95/100) = 950ml.

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

The current published toxico-pharmacological data indicates that liquid medical oxygen is not harmful to humans.

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 vessels 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 gas containers 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.

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 vessel storage area and the emergency services should be advised of the location of the vessel store.

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

6.5 Nature and contents of container

Liquid medical oxygen is stored either in a static vacuum insulated storage vessel or supplied in a portable cryogenic liquid vessel for homecare use.

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The liquid medical 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 aluminium 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 liquid medical 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 liquid medical oxygen to be vapourised and heated to ambient temperature prior to being 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.

Liquid medical oxygen is supplied to patients at home using Homecare liquid medical 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 liquid medical 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 liquid medical 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	Liquid 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 – vessels used for bulk liquid oxygen tanker deliveries

Vessel name	Gross water capacity (litres)	Nominal medical oxygen capacity (m^3)	Diameter (m)	Height (m)
VIE10	1480	844	1.38	3.35
VIE17	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

Hospital vessels – vessels used for bulk liquid oxygen tanker deliveries (continued)

Vessel name	Gross water capacity (litres)	Nominal medical Oxygen capacity (m^3)	Diameter (m)	Height (m)
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

Hospital vessels – vessels used for CRYOSPEED® (small tanker) deliveries

Vessel name	Gross water capacity (litres)	Nominal medical oxygen capacity (m^3)	Diameter (m)	Height (m)
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 and other handling

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 liquid medical oxygen vessel or from a portable liquid medical oxygen cylinder that has been filled from a Homecare vessel by the patient/carer. If using the Homecare liquid medical oxygen vessel directly the following instructions are applicable as to how to prepare the Homecare liquid medical oxygen vessel:
- Check contents gauge of the Homecare liquid medical 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 liquid medical 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 liquid medical oxygen vessel in order to fill the portable cylinder:
- Ensure that the connecting faces of the Homecare liquid medical oxygen vessel and the portable liquid medical oxygen cylinder are clean and free from oil or grease
- Check contents gauge of the Homecare liquid medical oxygen vessel to ensure there is enough liquid available to fill portable cylinder
- Firmly push portable liquid medical oxygen cylinder onto connector of the Homecare liquid medical 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 liquid medical oxygen cylinder is being filled
- Remove the portable liquid medical oxygen cylinder from the Homecare liquid medical 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 liquid medical oxygen cylinder and Homecare liquid medical oxygen vessel should be closed after use and when the unit is empty.

7. Marketing authorisation holder

BOC Ltd, The Priestley Centre, 10 Priestley Road, The Surrey Research Park,Guildford, Surrey GU2 7XY.

8. Marketing authorisation number(s)

PL 0735/0009R

9. Date of first authorisation/renewal of the authorisation

Date first granted: 01/09/1972

Date of renewal: 27/03/1992

10. Date of revision of the text

08/05/2019

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Supply classification status

1. Supply classification status

General Sales List.

Additional Safety Information

1. Contact information

BOC telephone number to be used in the event of an emergency
UK 0800 111 333

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 Preparations 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.

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HLC/505625/UKS/PGUK/0719