SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Oxygen.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen Ph. Eur. 100%.

3 PHARMACEUTICAL FORM

Inhalation gas.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypoxia of any cause. As diluent for gaseous and volatile anaesthetic agents.

4.2 Posology and method of administration

Use in adults and children

For respiratory use at concentrations of greater than 21%.

Use in neonates

When administering oxygen to neonates the inspired concentration of oxygen should not exceed 40%. (See **4.8**).

Use in the elderly

When giving oxygen to elderly chronic bronchitic patients the inspired concentration of oxygen should only be raised by 1% increments and should not exceed 30%.

Instructions for use and handling of Medical Oxygen equipment

1. Cylinder valves should be opened momentarily prior to use to blow any foreign matter out of the outlet.

2. Ensure that the connecting face on the yoke, manifold or regulator is clean and the sealing washer or ‘O’ ring where fitted is in good condition.

3. Cylinder valves must be opened slowly.

4. Only the appropriate regulator should be used for the particular gas concerned.

5. Pipelines for medical gases should be installed in accordance with the conditions set out in HTM 02.

6. Cylinder valves and any associated equipment must never be lubricated and must be kept free from oil and grease.

Leaks

1. Should leaks occur this will usually be evident by a hissing noise.

2. Leaks can be found by brushing the suspected area with an approved leak test solution.

3. There are no user serviceable parts associated with these valves, do not attempt to correct any problems with leakage from any part of the valve itself. Label any faulty containers, and return them to Air Liquide for repair.

4. Sealing or jointing compounds must never be used to cure a leak.

5. Never use excessive force when connecting equipment to cylinders.

Use of Medical Oxygen cylinders

1. Cylinders should be handled with care and not knocked violently or allowed to fall.

2. Cylinders should only be moved with the appropriate size and type of trolley.

3. When in use cylinders should be firmly secured to a suitable cylinder support.

4. Cylinders containing liquifiable gas must always be used vertically with the valve uppermost.

5. Medical gases must only be used for medicinal purposes.

6. Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.

7. After use cylinder valves should be closed using moderate force only and the pressure in the regulator or tailpipe released.

8. When only a small amount of gas remains in a cylinder, the cylinder valve must be closed. It is important to leave a small residual pressure in each cylinder after use, in order to protect the inside of the cylinder from contamination.

4.3 Contraindications

Normobaric oxygen therapy:
None

Hyperbaric oxygen therapy (HBOT):
Undrained/untreated pneumothorax (see section 4.4)

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.

High oxygen concentrations should be given for the shortest possible time required to achieve the desired result, and must be monitored with repeated checks of arterial gas pressure (PaO_2) or haemoglobin oxygen peripheral saturation (SpO_2) and clinical assessment.

Patients at risk of hypercapnic respiratory failure:

Special caution should be applied in patients with reduced sensitivity to the carbon dioxide tension in arterial blood or at risk of hypercapnic respiratory failure ("hypoxic drive") (e.g. patients with chronic obstructive pulmonary disease (COPD), cystic fibrosis, morbid obesity, chest wall deformities, neuromuscular disorders, overdose of respiratory depressant drugs). The administration of supplemental oxygen may cause respiratory depression and a rise in $PaCO_2$ with subsequent symptomatic respiratory acidosis (see section 4.8). In these patients, oxygen therapy should be carefully titrated; the target oxygen saturation to be achieved may be lower than in other patients and oxygen should be administered at a low flow rate.

Special caution in patients with bleomycin lung injury: the pulmonary toxicity of high-dose oxygen therapy can potentiate lung injury, even if given several years after the initial lung injury by bleomycin and the target oxygen saturation to be achieved may be lower than in other patients (see section 4.5).

Paediatric population:

Because of the higher sensitivity of newly born to supplemental oxygen, the lowest effective concentrations should be sought in order to achieve an adequate oxygenation appropriate for neonates (see section 4.2).

In preterm and newborn infants, increased PaO_2 may lead to retinopathy of prematurity (see section 4.8). It is recommended to start resuscitation of term or near term neonates with air instead of 100% oxygen. In preterm, the optimal concentration of oxygen and oxygen target are not precisely known. Supplemental oxygen, if required, will then be closely monitored and guided by pulse oximetry.

Hyperbaric oxygen therapy (HBOT):
Hyperbaric oxygen therapy should only be administered by qualified staff and in specialised centres aware and equipped for insuring appropriate precautions for hyperbaric use.
The pressure should be increased and reduced slowly in order to avoid the risk of pressure damage (barotrauma).

Confinement anxiety and claustrophobia can occur during the HBOT session chamber. The benefit/risk ratio of HBOT should be thoroughly evaluated in patients with claustrophobia, severe anxiety, psychosis.

Respiratory disorders:
Because of the decompression, at the end of the hyperbaric session, the gas volume increases while the pressure in the chamber decreases that may lead to partial pneumothorax or aggravation of an underlying pneumothorax. In a patient with an undrained pneumothorax, decompression could lead to the development of a tension pneumothorax. In cases of pneumothorax, pleural cavities must be drained before the session and it may be required to continue the drainage procedure during the HBOT session (see section 4.3).
Moreover, considering the risk of gas expansion during the decompression phase of HBOT, the benefit/risk ratio of HBOT should be thoroughly evaluated in patients with insufficiently controlled asthma, pulmonary emphysema, chronic obstructive pulmonary disease (COPD), recent thoracic surgery.

Diabetic patients: Blood glucose decrease during HBOT session has been reported. Hence, it may be preferable to monitor blood glucose before HBOT session in diabetic patients.

Coronary diseases: The benefit/risk ratio of HBOT should be thoroughly evaluated in patients with coronary diseases. In patients with acute coronary syndrome or acute myocardial infarction who also require HBOT, such as in case of CO intoxication, HBOT should be used cautiously because of the vasoconstriction potential of hyperoxia in the coronary circulation.

Ear, nose and throat disorders: In relation to the compression/decompression of HBOT, caution and thorough assessment of the benefit/risk ratio of HBOT are required in patients with sinusitis, otitis, chronic rhinitis, laryngocele, mastoid cavity, vestibular syndrome, hearing loss and recent middle ear surgery.

Relating to hyperoxia induced by HBOT, the benefit/risk ratio of HBOT should be thoroughly evaluated in patients with:

- History of seizure, epilepsy
- Uncontrolled high fever

Risk of fire:

Oxygen is an oxidizing product and promotes combustion. Whenever oxygen is used, the increased risk of fire ignition should be taken into account:

- Risk of fire in domestic environment: Patients and caregivers should also be warned about the risk of fire in presence of other sources of ignition (smoking, flames, sparkles, cooking, ovens etc.) and/or highly combustible substances, especially greasy substances (oils, grease, creams, ointments, lubricants etc.). Only water-based products should be used on the hands and face or inside the nose while using oxygen.
- Risk of fire in medical environment: this risk is increased in procedures involving diathermy, defibrillation and electro conversion therapy.
- Fires can occur at valve opening (frictional heating).

Thermal burns have occurred related to accidental fires in presence of oxygen.

Handling of the cylinders:

Caretakers and all people who handle medicinal oxygen cylinders should be warned about the need to carefully handle cylinders to prevent damages to the equipments, especially the valve. Equipment damage may cause obstruction of the outlet and/or wrong information displayed on the manometer or digital display with regards to remaining oxygen content and flow delivery leading to insufficient or lack of oxygen administration.

4.5 Interaction with other medicinal products and other forms of interaction

Inhalation of high concentration of oxygen can exacerbate the pulmonary toxicity associated with drugs such as bleomycin (even if oxygen is given several years after the initial bleomycin-induced lung injury), amiodarone, nitrofurantoin and with paraquat intoxication. Unless the patient is hypoxemic, supplemental oxygen should be avoided.

In the presence of oxygen, nitric oxide is rapidly oxidized to form superior nitrated derivatives that are irritant for the bronchial epithelium and the alveolocapillary membrane. Nitrogen dioxide (NO_2) is the principal compound formed. The oxidation rate is proportional to the initial concentrations of nitric oxide and oxygen in the inhaled air, and to the duration of contact between NO and O_2.

There is a risk of fire in the presence of other sources of ignition (smoking, flames, sparkles, ovens etc.) and/or highly combustible substances (oils, grease, creams, ointments, lubricants etc.) (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy:
In animal tests, toxicity to reproduction was observed after administration of oxygen at increased pressure or in high concentration. It is unknown to what extent these findings are relevant to humans.

Normobaric oxygen therapy:

Oxygen can be used during pregnancy only when necessary i.e. in case of vital indications, women either critically ill or with hypoxaemia.

Hyperbaric oxygen therapy (HBOT):

The amount of documented experience with the use of HBOT in pregnant women is limited, but has shown a benefit of HBOT for the foetus in case of CO intoxication in pregnant women. In other situations, HBOT should be used with caution in pregnancy as the impact on the foetus of a potential increase of oxidative stress from excess oxygen is unknown.

The use of HBOT should then be evaluated in each individual patient but is permissible in the case of vital indications during pregnancy.

Lactation:

Oxygen therapy can be used during breastfeeding without risk to the infant.

4.7 Effects on ability to drive and use machines

Normobaric oxygen therapy:
Oxygen has no influence on the ability to drive and use machines.

Hyperbaric oxygen therapy (HBOT):
Vision and hearing disorders which may affect the ability to drive and use machines have been reported after HBOT (see section 4.8).

4.8 Undesirable effects

Different tissues exhibit different sensitivities to hyperoxia, the most sensitive being the lungs, the brain and the eyes.

Description of selected adverse events:

Respiratory adverse events:

- At an ambient pressure, the first signs (tracheobronchitis, substernal pain and dry cough) appear as soon as after 4 hours of exposure to 95% oxygen. A reduced forced vital capacity can occur within 8-12h of exposure to 100% oxygen, but serious injuries require much longer exposures. Interstitial oedema can be seen after 18h of exposure to 100% oxygen and can lead to pulmonary fibrosis. Respiratory effects reported with HBOT are generally similar to those

encountered during normobaric oxygen treatment, but the time to symptom onset is shorter.

- With high concentrations of oxygen in the inspiratory air/gas, the concentration/pressure of nitrogen is reduced. As a result, the concentration of nitrogen in tissues and lungs (the alveoli) falls. If oxygen is taken up from the alveoli into the blood more rapidly than it is supplied in the inspiratory gas fraction, alveolar collapse can occur (development of atelectasis). The development of atelectatic sections of the lungs leads to a risk of poorer arterial blood oxygen saturation, despite good perfusion, due to lack of gas exchange in the atelectatic sections of the lungs. The ventilation/perfusion ratio worsens, leading to intrapulmonary shunt.

- There may be a change in the modalities of ventilation control in patients with long-term diseases associated with chronic hypoxia and hypercapnia. Under these circumstances, administration of too high concentrations of oxygen can cause respiratory depression, inducing aggravated hypercapnia, respiratory acidosis, and finally respiratory arrest (see section 4.4).

Central nervous toxicity:

- Central nervous toxicity can be observed in HBOT settings. Central nervous toxicity can develop when patients breathe 100% oxygen at pressures above 2 ATA. Early manifestations include blurred vision, peripheral vision decreased, tinnitus, respiratory disturbances, localised muscular twitching especially eyes, mouth, forehead. Continuation of exposure can lead to vertigo and nausea followed by altered behaviour (anxiety, confusion, irritability), and finally generalized convulsions. The hyperoxia-induced discharges are believed to be reversible, causing no residual neurological damage, and disappearing upon reduction of the inspired oxygen partial pressure.

Eye toxicity:

Progressive myopia has been reported in cases of multiple hyperbaric treatments. The mechanism remains obscure but an increase refractory index of the lens was suggested. Most cases were spontaneously reversible. However, risk of irreversibility increased after more than 100 therapies. After stopping HBOT, reversal of myopia was usually rapid for the first few weeks and then continued more slowly for periods ranging from several weeks to as long as a year. The threshold of number of HBOT sessions, periods or duration cannot be estimated. It was ranged from 8 to more than 150 sessions.

Pediatric population

In premature neonates who have been subjected to high oxygen concentrations, retinopathy of prematurity (retrolental fibroplasia) may occur at concentrations greater than 40%.

Risk of fire: The risk of fire is increased in presence of high concentrations of oxygen and sources of ignition potentially leading to thermal burns (see section 4.4).

Adverse events related to HBOT procedure:

- Undesirable effects of HBOT are barotraumas or consequences of multiple and rapid compressions/decompressions. Most of them are not specific to the use of oxygen and can occur in patients under oxygen as well as in attending healthcare professionals under hyperbaric ambient air. These are ear, sinuses and throat barotraumas, pulmonary barotraumas, other barotraumas (teeth, etc.).

- Due to the relatively small size of some hyperbaric chambers, patients may develop confinement anxiety that is not due to a direct effect of oxygen.

Adverse reactions associated with Oxygen Therapy:

	Very common (> 1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)	Not known
Respiratory, thoracic and mediastinal disorders			Atelectasis			Pulmonary toxicity: • Tracheobronchitis (substernal pain, dry cough) • Interstitial oedema • Pulmonary fibrosis Worsening of hypercapnia in patients with chronic hypoxia/hypercapnia treated with too much elevated FiO_2: • Hypoventilation • Respiratory acidosis • Respiratory arrest
Eye disorders	Retinopathy of prematurity					
General disorders and administration site conditions						Mucosal dryness Local irritation and inflammation of the mucosa

Adverse reactions specific to Hyperbaric Oxygen Therapy:

	Very common (> 1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)	Not known

	Very common (> 1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)	Not known
Respiratory, thoracic and mediastinal disorders				Dyspnoea		Respiratory disturbances
Nervous system disorders		Seizure				
Musculoskeletal and connective tissue disorders						Localised muscular twitching
Ear and labyrinth disorders	Ear pain		Tympanic membrane rupture			Vertigo Hearing impaired Acute serous otitis media Tinnitus
Gastrointestinal disorders						Nausea
Psychiatric disorders						Abnormal behaviour
Eye disorders	Progressive myopia					Peripheral vision decreased Blurred vision Cataract*
Injury, poisoning and procedural complications	Barotrauma (sinuses, ear, lung, teeth etc.)					
Metabolism and nutrition disorders				Hypoglycemia in diabetic patients		

* The development of cataracts has been reported in patients undergoing prolonged courses and/or frequently repeated sessions of HBOT (> 150 sessions). Some cases of de novo/new cataract have been observed.

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 Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of oxygen intoxication are those of hyperoxia.
The symptoms of respiratory toxicity include from tracheobronchitis (substernal pain, dry cough) to interstitial oedema and pulmonary fibrosis.
The symptoms of central nervous toxicity that are observed in HBOT settings, include tinnitus, respiratory disturbances, localized muscular twitching especially eyes, mouth, forehead. Continuation of exposure can lead to vertigo and nausea followed by altered behaviour (anxiety, confusion, irritability), and finally generalized convulsions.

Eye toxicity includes blurred vision and reduced peripheral vision within HBOT settings.

Paediatric population:
Eye toxicity in neonates: in premature neonates who have been subjected to high oxygen concentrations, retinopathy of prematurity may occur.

Patients at risk of hypercapnic respiratory failure:
The administration of supplemental oxygen may cause respiratory depression and a rise in $PaCO_2$ with subsequent symptomatic respiratory acidosis.

In case of oxygen intoxication related to hyperoxia, oxygen therapy should be reduced or if possible stopped, and symptomatic treatment should be started.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oxygen is a colourless, odourless gas with molecular weight 32, a boiling point of -183.1^{o}C (at 1 bar) and a density of 1.355 kg/m^{3} (at 15^{o}C and 1013mb).
Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

There are no additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

There are no incompatibilities with oxygen in clinical practice.

6.3 Shelf life

Five years.

6.4 Special precautions for storage

Cylinders should be kept out of the reach of children.

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, greases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.

The normal precautions required in the storage of medical gas cylinders as described below are applicable.

- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- Cylinders should not be stored near stocks of combustible materials or near sources of heat.
- Warning notices prohibiting smoking and naked lights must be posted clearly.
- Emergency services should be advised of the location of the cylinder store.
- Medical cylinders containing different gases should be segregated and identified within the store.
- Full and used cylinders should be stored separately. Full cylinders should be used in strict rotation.
- Cylinders must not be repainted, have any markings obscured or labels removed.
- F size cylinders and larger should be stored vertically E size cylinders and smaller should be stored horizontally.
- Precautions should be taken to protect cylinders from theft.

6.5 Nature and contents of container

Oxygen is supplied in a gas cylinder, with valve, suitable for the pressure required for the product.

The types of cylinders normally used are specified in the following table.

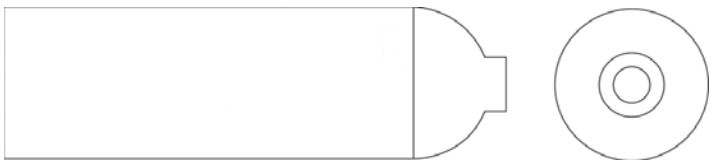
Cylinder Size	Water Volume (litres)	Fill Pressure (bar)	Fill Volume (m^3)	Valve Type (1)
CC	1.0	300	0.30	4 bar outlet, Schraeder connector plus flow control
PD	2.0	137	0.30	Bullnose 5/8” BSP female, top outlet
PD4C	2.0	200	0.43	4 bar outlet, Schraeder connector plus flow control
AD	2.0	230	0.49	4 bar outlet, Schraeder connector plus flow control
D	2.32	137	0.34	Pin-index
DI	2.32	230	0.565	4 bar outlet, Schraeder connector plus flow control
E	4.68	137	0.68	Pin-index
AE	5.0	137	0.74	Pin-index
F	9.43	137	1.36	Bullnose 5/8” BSP female, top outlet
F4C	9.43	230	2.30	4 bar outlet, Schraeder connector plus flow control
AF	10.0	137	1.44	Bullnose 5/8” BSP female, top outlet
G	23.6	137	3.40	Bullnose 5/8” BSP female, top outlet
G4C	23.6	230	5.70	4 bar outlet, Schraeder connector plus flow control
SJ	50	137	7.30	Pin-index
J	50	200	10.60	Pin-index, pressure reducing 137 bar outlet
J200	50	200	10.60	Pin-index
HC01	1.0	230	0.23	4 bar outlet, Schraeder connector
HC02	2.0	230	0.49	4 bar outlet, flow control
HC104C	10.0	200	2.1	4 bar outlet, Schraeder connector plus flow control

Cylinder Size	Water Volume (litres)	Fill Pressure (bar)	Fill Volume (m^3)	Valve Type [1]
HC02HQ	2.0	230	0.49	4 bar outlet, quick connect plus flow control
HC10HQ	10	200	2.1	4 bar outlet, quick connect plus flow control
PD490GQ	2.0	230	0.49	4 bar outlet, quick connect plus flow control
PD430C	2.0	200	0.43	4 bar outlet, flow control
CB430Q	2.0	200	0.43	4 bar outlet, quick connect plus flow control
HC10BU	10.0	137	1.36	4 bar outlet, flow control
AD 300	2.0	300	0.64	4 bar outlet, quick connect plus flow control
B104C	10	200	2.1	4 bar outlet, quick connect plus flow control
B104C 230	10	230	2.42	4 bar outlet, quick connect plus flow control
HC02BU	2	200	0.49	4 bar outlet, quick connect plus flow control
Oyan Smart	2.0	200	0.43	4 bar outlet, Schraeder connector plus flow control

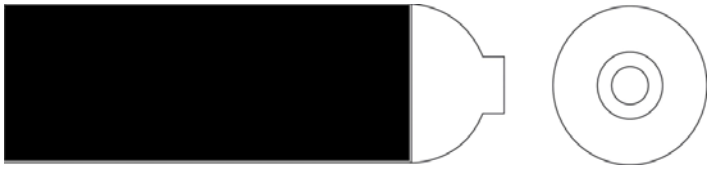
Note: (1) Cylinder valves conform to BS341 (non pin-index – except the 4bar outlet valves which are proprietary) and BS EN ISO 407 (pin-index)
(2) N.B. Cylinders with 200 bar pressure at the outlet, and should only be used on a manifold installed to HTM 02, or with a 200 bar regulator.

The colour of Medical Oxygen cylinders in the UK is in a period of change. The colour coding of the shoulder of Medical Oxygen is white. The body of the cylinder will be either black or white.

The aim is to complete a period of change over from the black body to the white bodied cylinder. The shoulder colour of the cylinder will remain as white. This period of change will be completed by January 1st 2028. The images below represent the new and current colour coding of Medical Oxygen cylinders.



New white bodies Medical Oxygen cylinder colour coding.



Current Medical Oxygen cylinder colour coding.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and handling

Cylinders that are no longer required should be returned to Air Liquide.

See section 4.2 for 'Instructions for use and handling of Medical Oxygen equipment'.

When using containers that have a digital display, check there is a readout displayed on the screen. If there is no readout displayed, do not use the container.

Cylinders with digital displays will have alarmed set points for contents remaining.

7 MARKETING AUTHORISATION HOLDER

Air Liquide Ltd
Station Road
Coleshill
Birmingham
West Midlands
B46 1JY

8 MARKETING AUTHORISATION NUMBER(S)

PL 15929/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th February 1998 / 17th April 2003

10 DATE OF REVISION OF THE TEXT

06/05/2026