

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Oxygen

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Compressed Medical Oxygen cylinders are supplied to the following specification:
Compressed Medical Oxygen Purity 99.5%(min)

The Compressed Medical Oxygen cylinder specification complies with the current European Pharmacopoeia monograph (0417).

3 PHARMACEUTICAL FORM

Medicinal gas, compressed.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Medical Oxygen is widely used in clinical practice to:

- provide a basis for most modern anaesthetic techniques including pre and postoperative management.
- 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
 - 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
- aid in the resuscitation of the critically ill, when the circulation is impaired
- aid in neo-natal resuscitation
- treat acute severe headache in adults diagnosed with cluster headache

4.2 Posology and method of administration

Medical Oxygen is administered by 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.

For cluster headache, oxygen should be administered as soon as possible after the onset of the attack, via a non-rebreathing facemask at a flow of 6 to 12 l/min for approximately 15 minutes.

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 Medical 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.

Careful monitoring of oxygen levels on the breath, blood and tissue is required 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 additional oxygen should be avoided.

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

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

Compressed Medical Oxygen Cylinders should be set up and tested before placing near the patient. Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.

Smoking should be prohibited when using Compressed Medical Oxygen.

Under no circumstances should oils or grease be used to lubricate any part of the Compressed Medical Oxygen cylinder 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 Compressed Medical Oxygen cylinders or equipment.

4.5 Interaction with other medicinal products and other forms of interaction

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

6.3 Shelf life

3 years

6.4 Special precautions for storage

Compressed Medical Oxygen cylinders should be:

- stored under cover, preferably inside, kept dry and clean, and not subjected to extremes of heat or cold 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
- F size cylinders and larger should be stored vertically. E size cylinders and smaller should be stored horizontally.

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 store.

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

6.5 Nature and contents of container

A summary of Medical Oxygen cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed below:

Cylinder Details				Valve details		
Size	Gas Content (litres)	Water Capacity (Litres)	Material of Construction	Filling Port	Valve Type Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
AZ	170	1.2	Aluminium	Valve Type	Non Regulated	137
				Outlet	Pin Index (BS EN 850)	
ZA	300	1.0	Aluminium (Carbon Fibre hoop wrapped)	Valve Type	Integral Regulated	4
				Filling Port	ISO 5145 (Oxygen)	
				Outlet	6 mm Fir Tree	
				Flowrate	0.1 – 15 litres/min	
D	340	2.32	Steel	Valve Type	Non Regulated	137
				Outlet	Pin Index (BS EN 850)	

Cylinder Details				Valve details		
Size	Gas Content (litres)	Water Capacity (Litres)	Material of Construction	Filling Port	Valve Type Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
CD	460	2.0	Aluminium (Kevlar hoop wrapped)	Valve Type	Integral Regulated	4
				Filling Port	ISO 5145 (Oxygen)	
				Outlet (1)	6mm Fir Tree	
				Flowrate	1 - 15 litres/min	
				Outlet (2)	BS 5682 Schrader	
				Flowrate	40 litres/min (max)	
DD	460	2.0	Steel	Valve Type	Integral Regulated	4
				Filling Port	ISO 5145 (Oxygen)	
				Outlet	6mm Fir Tree	

				Flowrate2, 4 litres/min	
ZD	605	2.0	Aluminium (Carbon Fibre hoop wrapped)	Valve TypeIntegral Regulated Filling PortISO 5145 (Oxygen) Outlet (1)6 mm Fir Tree Flowrate1 - 15 litres/min Outlet (2)BS 5682 Schrader Flowrate40 litres/min (max)	4
E	680	4.68	Steel	Valve TypeNon Regulated OutletPin Index (BS EN 850)	137

Cylinder Details				Valve details	
Size	Gas Content (litres)	Water Capacity (Litres)	Material of Construction	Valve Type Filling Port Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)
F	1360	9.43	Steel	Valve TypeMPR Non Regulated OutletBS 341 No.3 (Top)	137
AF	1360	9.43	Aluminium / Steel	Valve TypeMPR Non Regulated OutletBS 341 No.3 (Top)	137
DF	1360	9.43	Aluminium / Steel	Valve TypeIntegral Regulated Filling PortISO 5145 (Oxygen) Outlet6mm Fir Tree Flowrate2, 4 litres/min	4
HX	2300	10.0	Steel	Valve TypeIntegral Regulated Filling PortISO 5145 (Oxygen) Outlet (1)6mm Fir Tree Flowrate1 - 15 litres/min	4

				Outlet (2) Flowrate	BS 5682 Schrader 40 litres/min (max)	
ZH	2400	8.0	Steel (Carbon Fibre hoop wrapped)	Valve Type Filling Port Outlet (1) Flowrate Outlet (2) Flowrate	Integral Regulated ISO 5145 (Oxygen) 6mm Fir Tree 1 – 15 litres/min BS 5682 Schrader 40 litres/min (max)	4
ZX	3040	10.0	Steel (Carbon Fibre hoop wrapped)	Valve Type Filling Port Outlet (1) Flowrate Outlet (2) Flowrate	Integral Regulated ISO 5145 (Oxygen) 6mm Fir Tree 1 - 15 litres/min BS 5682 Schrader 40 litres/min (max)	4

Cylinder Details				Valve details		
Size	Gas Content (litres)	Water Capacity (Litres)	Material of Construction	Valve Type Filling Port Outlet Connections Outlet Flowrates	Nominal Valve Outlet Pressure Bar(g)	
G	3400	23.6	Steel	Valve Type MPR Non Regulated Outlet BS 341 No.3 (Top)	137	
J	6800	47.2	Steel	Valve Type Non Regulated Outlet Pin Index (BS EN 850)	137	
W	11300	46.6	Steel	Valve Type Non Regulated Outlet ISO 5145 (Oxygen)	230	

Cylinders

All cylinders used for the storage of Medical Oxygen are manufactured from either high tensile steel or aluminium. The AZ, D, E, F, AF, DF, G and J size cylinders are designed with working pressure of at least 137 bar(g) The CD, DD, HX and W size cylinders are designed with a maximum working pressure of 230 bar (g). The ZA, ZD, ZH and ZX size cylinder are designed with a maximum working pressure of 300 bar(g).



The colour coding of the shoulders of Compressed Medical Oxygen cylinders is white (RAL 9010).

The colour coding of the cylinder body is white (RAL 9010). Cylinders also carry the oxygen name on the body of the cylinder.

For a limited period, cylinders may have black bodies. These cylinders do not have the name oxygen on the body of the cylinder.

The programme to convert all Compressed Medical Oxygen cylinders to white bodies will be completed by 2025.

Cylinder Valves

Medical Oxygen cylinders are supplied with two main types of cylinder valves, dependent upon the cylinder filling pressure and the type of application.

Conventional cylinder valves are fitted to AZ, D, E, F, AF, G and J cylinders which are designed to be used with a pressure regulator. All of these cylinders are fitted with valves with outlet connections that conform to either ISO 407 (pin index) or BS 341 (5/8" BSP F) and are filled to 137 bar(g). The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

The side outlet hand wheel valve fitted to W cylinders has an ISO 5145 product specific valve outlet. The valve design incorporates a residual pressure device to prevent the cylinder from being fully emptied and prevent the cylinder from being contaminated should the valve be left open. The valve can be filled to 230 bar (g). The valve is constructed from brass and is fitted with a brass spindle with a Nylon 6.6 insert. The residual pressure device is fitted with EDPM O-ring seals.

ZA, ZD, CD, DD, DF, ZH, HX and ZX cylinders are fitted with valves that have an integral pressure regulator, with an outlet pressure of 4 bar(g). These regulated valves are fitted with an ISO 5145 product specific filling connection and either a product specific BS 5682 Schrader outlet connection or a standard 6mm fir tree outlet. Integral cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

The internal valve components in the integral regulated valve are made from oxygen compatible materials, designed to not produce poisonous fumes if the cylinder is subjected to high temperatures, causing ignition of any of the valve components.

Cylinders for use with MRI Scanners

The AZ Medical Oxygen cylinder shell is manufactured from aluminium and the valve from high tensile brass and other non-magnetic components that are not attracted by high magnetic fields. The AZ Medical Oxygen cylinder label carries the statement 'Suitable for use with MRI scanners' and is the only package that is specified as suitable for use within the vicinity of MRI scanners.

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 Medical Oxygen cylinders should have adequate knowledge of:

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

Preparation for Use

Cylinders used with a pressure regulator

Sizes AZ, D, E, F, AF, G, J and W

To prepare the cylinder for use, before placing near the patient:

- remove the tamper evident seal and the valve outlet protection cap. Ensure the cap is retained so that it can be refitted after use.
- ensure the batch label fitted to the cylinder is not removed or discarded
- ensure that an appropriate Medical Oxygen regulator or manifold tailpipe is selected for connection to the cylinder.
- ensure the connecting face on the regulator is clean and the sealing washer fitted is in good condition.
- connect the regulator or tailpipe, using moderate force only and where appropriate connect the tubing to the regulator / flowmeter outlet. Only the appropriate regulator should be used for the particular gas concerned.
- open the cylinder valve slowly and check for any leaks

Cylinders with an integral regulated valve

Sizes ZA, ZD, CD, DD, DF, ZH, HX and ZX

To prepare the cylinder for use, before placing near the patient:

- check the cylinder contents gauge on the cylinder valve to ensure that there is sufficient gas contents in the cylinder.
- remove the tamper evident seal and cover fitted over the valve outlets.
- ensure the batch label fitted to the cylinder is not removed or discarded.
- ensure that the correct equipment is selected for connection to the cylinder. The tubing should be designed for use with medical oxygen and the Schrader probe should be specific to Medical Oxygen use.

Connect as appropriate either:

- the appropriate sized tubing to the fir tree outlet or
- the Medical Oxygen Schrader probe to the Schrader outlet (where fitted)
- open the cylinder valve slowly and check for any leaks

Leaks

Cylinders used with a pressure regulator

Sizes AZ, D, E, F, AF, G, J and W

Having connected the regulator or manifold yoke/connector to the cylinder check the connections for leaks using the following procedure:

- Should leaks occur this will usually be evident by a hissing noise.
- If a leak occurs between the valve outlet and the regulator or manifold yoke/connector, depressurise and remove the fitting and fit an approved sealing washer. Reconnect the fitting to the valve with moderate force only, fitting a replacement regulator or manifold tailpipe as required.
- Sealing or jointing compounds must never be used to cure a leak.
- Never use excessive force when connecting equipment to cylinders.
- If leak persists, label cylinder and return to BOC.

Cylinders with an integral regulated valve
Sizes ZA, ZD, CD, DD, DF, ZH, HX and ZX

Check the connection for leaks using the following procedure:

- Should leaks occur this will usually be evident by a hissing noise.
- Close valve, remove connection, check and refit.
- Never use excessive force when connecting equipment to cylinders.
- If leak persists label cylinder and return to BOC

Use of Cylinders

When Medical Oxygen cylinders are in use ensure that they are:

- only used for medicinal purposes.
- 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.
- used with an appropriately designed cylinder support to hold the cylinder whilst in use adjacent to the patient.
Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.
- where the cylinder is being used in accident and emergency/ambulance situations the cylinder should only be placed on the trolley after the valve has been turned on and the flow rate set.
- not allowed to have any markings, labels or batch labels obscured or removed.
- firmly secured to a suitable cylinder support when in use.
- not used in the vicinity of persons smoking or near naked lights.

Use of Cylinders with MRI Scanners

When Medical Oxygen cylinders are required to be used in the vicinity of MRI scanners, they should be tested with the appropriate equipment to ensure that they have no components that are attracted by high magnetic fields.

It is recommended that only AZ Medical Oxygen cylinders are used in the vicinity of MRI scanners.

After Use

Cylinders used with a pressure regulator

Sizes AZ, D, E, F, AF, G, J and W

When the Compressed Medical Oxygen cylinders are empty ensure that the:

- Cylinder valve is closed using moderate force only and the pressure in the regulator or tailpipe released.
- Valve outlet cap, where fitted, is replaced

Cylinders with an integral regulated valve

Sizes ZA, ZD, CD, DD, DF, ZH, HX, and ZX

When the Compressed Medical Oxygen cylinders are turned off or empty ensure that the:

- Cylinder valve is closed slowly using moderate force
- Valve is allowed to vent before turning the flow selector to zero
- Equipment is disconnected
- Valve outlet cap, where fitted, is replaced

Empty cylinders must be returned immediately to an empty cylinder storage area for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Gases Ireland Limited
 J F Kennedy Drive
 Bluebell
 Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA0208/003/001

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

December 2016

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable