BOC
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Medical Gas Data Sheet (MGDS)
Medical oxygen (compressed gas)

Essential safety information

BOC: Living healthcare

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Medical oxygen (compressed gas) SPC

1. Name of the medicinal product

Compressed 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.

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.

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.

4.3 Contraindications

There are no absolute contraindications to the use of medical 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 3bar(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.

Oxygen supports combustion, naked flames and smoking is prohibited when medical oxygen is in use.

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 the facemask etc. only an approved cream should be used and under no circumstances should oil based creams be used. Check that hands are clean and free from any oils or grease.

Care is needed when handling and using compressed medical oxygen cylinders.

4.5 Interaction with other medicinal products and other forms of interaction

High-dose oxygen may increase the risks of amiodarone-induced postoperative adult respiratory distress syndrome. Pulmonary toxicity can develop in patients treated with bleomycin who are exposed to conventional oxygen concentrations during anaesthesia. High oxygen fraction may potentiate pulmonary toxicity caused by exposure to agents such as paraquat which are toxic to the lung.

4.6 Pregnancy and lactation

Medical 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

Compressed medical 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 3bar(g)
- retrosternal soreness associated with coughing and breathing difficulties, made worse by smoking and exposure to cold air after breathing pure medical oxygen at atmospheric pressure for several hours.

4.9 Overdose

Overdose effects for medical oxygen are detailed 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	32.00
boiling point	-183.1°C (at 1bar(g))
density	1.335kg/m^3 (at 15°C).

Oxygen is present in the atmosphere at 21% and is an essential 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 available to the body.

It can be expressed as the product of cardiac output and the blood's oxygen content.

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 medical oxygen is not harmful to humans.

6. Pharmaceutical particulars

6.1 List of excipients

None.

6.2 Incompatibilities

Medical oxygen strongly supports combustion and will cause substances to burn vigorously, 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 in the presence of oxygen in relatively high concentrations.

6.3 Shelf life

36 months.

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 compressed medical oxygen cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed opposite.

Cylinder size	Gas content (litres)	Cylinder water capacity (litres)	Cylinder construction	Valve type Filling port Outlet connections Outlet flowrates		Nominal valve outlet pressure bar(g)
AZ	170	1.2	Aluminium	Valve type Outlet	Non regulated Pin Index (BS EN 850)	137
C	170	1.2	Steel	Valve type Outlet	Non regulated Pin Index (BS EN 850)	137
ZA	300	1.0	Aluminium (Carbon fibre hoop wrapped)	Valve type Filling port Outlet Flowrate	Integral regulated ISO 5145 (oxygen) 6mm Fir Tree 0.1-15 litres/min	4
ZB	300	1.0	Steel (Carbon fibre hoop wrapped)	Valve type Filling port Outlet Flowrate	Integral regulated ISO 5145 (oxygen) 6mm Fir Tree 1-15 litres/min	3
ZC	300	1.0	Steel (Carbon fibre hoop wrapped)	Valve type Filling port Outlet Flowrate	Integral regulated ISO 5145 (oxygen) 6mm Fir Tree 0.1-5 litres/min	3
D	340	2.32	Steel	Valve type Outlet	Non regulated Pin Index (BS EN 850)	137
AD	460	2.0	Steel	Valve type Filling port Outlet Flowrate	Integral regulated ISO 5145 (oxygen) 6mm Fir Tree 8 litres/min	4
CD	460	2.0	Aluminium (Kevlar 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
DD	460	2.0	Steel	Valve type Filling port Outlet Flowrate	Integral regulated ISO 5145 (oxygen) 6mm Fir Tree 2, 4 litres/min	4
PD	300	2.0	Steel	Valve type Outlet	MPR Non regulated BS 341 No.3 (Top)	137

Cylinder size	Cylinder content (litres)	Gas water capacity (litres)	Cylinder construction	Valve type Filling port Outlet connections Outlet flowrates		Nominal Valve outlet pressure bar(g)
SD	300	2.0	Steel	Valve type Outlet	Non regulated Pin Index (BS EN 850)	137
ZD	605	2.0	Aluminium (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
E	680	4.68	Steel	Valve type Outlet	Non regulated Pin Index (BS EN 850)	137
F	1360	9.43	Steel	Valve type Outlet	MPR non regulated BS 341 No.3 (Top)	137
AF	1360	9.43	Aluminium / Steel	Valve type Outlet	MPR non regulated BS 341 No.3 (Top)	137
DF	1360	9.43	Aluminium / Steel	Valve type Filling port Outlet Flowrate	Integral regulated ISO 5145 (oxygen) 6mm Fir Tree 2, 4 litres/min	4
HX	2300	10.0	Steel	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
ZH	2430	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
G	3400	23.6	Steel	Valve type Outlet	MPR non regulated BS 341 No.3 (Top)	137
J	6800	47.2	Steel	Valve type Outlet	Non regulated Pin Index (BS EN 850)	137

Cylinders

All cylinders used for the storage of compressed medical oxygen are manufactured from either high tensile steel or aluminium.

The AZ, C, D, PD, SD, E, F, AF, DF, G and J size cylinders are designed with working pressure of at least 137bar(g).

The AD, CD, DD, and HX size cylinders are designed with a maximum working pressure of 230bar(g).

The ZA, ZB, ZC, ZD, ZH and ZX size cylinders are designed with a maximum working pressure of 300bar(g).

Cylinder valves

Compressed 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, C, D, PD, SD, 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 137bar(g). The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert.

ZA, ZB, ZC, ZD, AD, CD, DD, DF, ZH, HX and ZX cylinders are fitted with valves that have an integral pressure regulator, with an outlet pressure of 3 or 4bar(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.

6.6 Special precautions for disposal and other handling

All personnel handling compressed 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, C, D, PD, SD, E, F, AF, G and J.

To prepare the cylinder for use:

- remove the tamper evident seal and the valve outlet protection cap. Ensure the cap is retained so that it can be refitted after use.
  Do not remove and discard any batch labels fitted to the cylinder.
- ensure that an appropriate compressed medical oxygen regulator 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, using moderate force only and 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 leak.

Cylinders with an integral regulated valve

Sizes ZA, ZB, ZC, ZD, AD, CD, DD, DF, ZH, HX and ZX.

To prepare the cylinder for use:

- 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 that the correct equipment is selected for connection to the cylinder.

Connect as appropriate either:

- the appropriate sized tubing to the fir tree outlet
- 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, C, D, PD, SD, E, F, AF, G and J.

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

- should leaks occur this will usually be evident by a hissing noise
- should a leak occur between the valve outlet and the regulator or manifold yoke, 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
- if leak persists, label cylinder and return to BOC.

Cylinders with an integral regulated valve

Sizes ZA, ZB, ZC, ZD, AD, 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 compressed 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
- 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 compressed medical oxygen cylinder is 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
- empty cylinders are immediately returned to the empty cylinder store for return to BOC.

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 0735/5000.

9. Date of first authorisation/renewal of the authorisation

Date first granted: 01/09/1972.
Date of renewal: 21/07/1997.

10. Date of revision of the text

Date of revision: 11/2009.

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

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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 Substances Directive

Contact with combustible material may cause fire (R8).
Keep out of the reach of children (S2).
Keep away from combustible material (S17).

Label statements

- Contact with combustible material my cause fire.
- No smoking or naked flames near medical oxygen cylinders.
- Use no oil or grease.
- Keep away from extremes of heat and combustible material.
- Store cylinders under cover in a clean, dry and well ventilated area.

Medical oxygen is supplied as a compressed gas in a high pressure cylinder.
Cylinders may explode if subjected to extremely high temperatures (if involved in a fire).
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 medical oxygen cylinders are involved in a fire:

- if it is safe to move the cylinders,
  - close cylinder valve to stop the flow of product
  - move cylinders away from source of heat
- if it is not safe to move the cylinders,
  - cool with water from a protected position.

All types of fire extinguishers may be used when dealing with a fire involving 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 medical oxygen is released, if safe to do so, you should:

- close the cylinder valve
- where possible, isolate all sources of ignition
- if release continues, evacuate the area and ensure that the affected area is adequately ventilated before re-entry.

Self-contained breathing apparatus is not required to be used if oxygen is released in a confined area.

5. Exposure controls

When using medical oxygen cylinders 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.

6. Disposal considerations

It is recommended that medical oxygen cylinders should not be vented after use – they should be returned to BOC, with any residual gas, where they will be vented before refilling in a safe environment.

If, for safety reasons, a cylinder is required to be vented after use, the gas should be vented to atmosphere in a well ventilated area.

Contact BOC if further guidance on venting cylinders is required.

7. Transport of cylinders

When medical oxygen cylinders are required to be transported, ensure that the cylinders are:

- located in a compartment separated from the driver
- adequately restrained
- not leaking and have their valves closed.

The vehicle must be adequately ventilated. Ensure the driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency.

It is advisable to provide the driver with written instructions that detail the actions to be taken in the event of an accident or emergency. Cylinders should be removed from the vehicle as soon as possible.

8. Use of cylinders in transit – advice to patient/carer

If you need to use medical oxygen within a vehicle, you are advised to:

- prohibit smoking in the vehicle
- only carry the minimum number of cylinders to provide sufficient gas for patient use during the journey/activity
- ensure all cylinders are adequately restrained
- keep cylinder valves closed when not in use
- avoid using the cylinder when the vehicle is being refuelled
- set the ventilation system to fresh air or open a window to provide adequate ventilation and to prevent oxygen enrichment within the vehicle
- avoid leaving cylinders unattended in a vehicle. Unless the vehicle is specifically designed to carry medical oxygen cylinders,they should be removed from the vehicle overnight.

9. Transport information

UN Number:	UN1072 oxygen, compressed
Material:	Class 2
Labels:	2.2, 5.1
Hazard identification number:	25
Emergency Action Code:	2S
Tunnel Restriction Code:	E
Transport category:	3

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