

# Medical Oxygen (O<sub>2</sub>)

## **PRESENTATION**

#### Pharmaceutical form

Compressed medical gas (for medicinal use only)

# **Specification**

Complies with European Pharmacopoeia specifications 1985

Purity 99.5% (min)
Carbon dioxide 300.0vpm (max)
Carbon Monoxide 5.0vpm (max)

## Physical data

Molecular weight 32.00
Physical State in cylinder Gas
Specific Gravity of gas at 15°C and 1013mb 1.106

Density of Gas at 15°C and 1013mb 1.355kg/m<sup>3</sup>

Combustion characteristics Non flammable. Strongly supports

combustion

## USES

Modern anaesthetic practice is almost totally dependent on oxygen which provides a dimension of safety that makes possible some of the complicated medical manoeuvres required by modern surgery, and without which the risks would be too great to justify the method.

Of equal value is the use of oxygen in intensive care units where it provides the main life-saving support, particularly for patients whose lungs need to be artificially ventilated if they are to survive.

Although the immediate management of cardiac arrest does not depend on an oxygen supply other than in the ambient air, continued treatment almost invariably depends on artificial ventilation with supplementary oxygen.

The use of oxygen in chronic respiratory and cardiac conditions is very often essential and it is needed for the relief of all forms of hypoxia other than histotoxic. In short, modern medicine could not be practiced without the support that oxygen provides.

#### Oxygen is widely used:

- in clinical practice to provide a basis for virtually all modern anaesthetic techniques as well as pre and post-operative management.
- to restore the tissue oxygen tension towards normal by improving oxygen availability in a wide range of conditions, such as:
  - cyanosis of recent origin as a result of cardio-pulmonary disease
  - surgical trauma, chest wounds and rib fractures
  - shock, severe haemorrhage and coronary occlusion
  - carbon monoxide poisoning
  - hyperpyrexia
  - major trauma, eg. 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.

## DOSAGE AND ADMINISTRATION

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

The fundamental indication is the presence of hypoxia due to whatever cause.

Modern oxygen usage requires seperate devices for administering the gas in high and in low concentrations. The lowest concentration should not fall below that present in ambient air (20.9%).

These devices have been classified as follows:

# Fixed Performance Systems (patient-independent)

- high flow-venti masks.
- low flow-anaesthetic circuits.

In all these systems the oxygen concentration is pre-determined by the clinician.

## Variable Performance Systems (patient dependent)

- without re-breathing-catheters and cannulae.
- with re-breathing through a face mask such as the MC Edinburgh and Pneumask.

These systems only function by means of the patient who creates the inspired mixture by the act of breathing. Various patient and device factors influence the result.

Special care is needed when oxygen is administered:

- to neonates where the inspired concentration should not exceed 40% because of the risk of retrolental 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 and other central nervous system (CNS) effects may occur at 2 atmospheres or more, after a few hours exposure to pure oxygen. At higher pressures more rapid onset of CNS symptions will occur.

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

Almost invariably, oxygen is administered through the lungs by inhalation. The major exception is when a metered supply is fed into the oxygenator of the extracorporeal circulation of a cardio-pulmonary by-pass system.

# **CONTRA-INDICATIONS, WARNINGS ETC**

There are no absolute contra-indications 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.

## Interactions with other medicaments and other forms of interaction

The pharmacokinetic activity of oxygen is modified by changes in the blood carbon dioxide tension but this has little clinical significance.

## Effects on ability to drive and to 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.

## Other undesirable effects (frequency & seriousness)

Oxygen toxicity can occur as manifested by:

- retrolental fibroplasia in premature infants exposed to oxygen concentrations greater than 40%.
- central nervous system 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.

#### Use in pregnancy and lactation

Oxygen does not adversely affect pregnancy and lactation.

#### Other special warnings and precautions

Oxygen supports combustion and smoking should be prohibited when oxygen is in use and no naked flame should be allowed.

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

## Overdose (symptoms, emergency procedures, antidotes)

As detailed in 'Other undesirable effects'.

## Incompatibilities (major)

There are no incompatibilities with oxygen in clinical practice.

# PHARMACEUTICAL PRECAUTIONS

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 and use of medical gas cylinders are applicable. These are fully explained in the associated brochure 'Gas Safe — in the hospital' and on the reverse of this Data Sheet.

United Nations Substance

#### Occupational exposure standard (OES)

There is no OES for medical oxygen in the U.K.

# **LEGAL CATEGORY**

General sales list.

# PACKAGE QUANTITIES

#### Cylinder data

Colour code (BS 1319C):

Body colour — Black Shoulder colour — White 137 bar (max) at 15°C

Cylinder pressure:

Cyl size	Valve type	Valve outlet connection	Nominal contents <sup>1</sup> (litres)	Nominal weight of gas <sup> </sup> (kg)	Approx cylinder weight <sup>2</sup> (kg)	Approx cylinder dimensions <sup>3</sup> (mm)
С	Pin index	Yoke fitting	170	0.23	2.0	430 x 89
PD	Bull nose	<sup>5</sup> 8" BSP (f)	300	0.41	4.8	455 × 100
SD	Pin index	Yoke fitting	300	0.41	3.1	430 × 100
D	Pin index	Yoke fitting	340	0.46	3.4	535 × 102
AD <sup>4</sup>	Starvalve	6 mm firtree	460	0.55	4.1	480 × 100
RD <sup>4</sup>	Starvalve	6 mm firtree <sup>5</sup>	460	0.55	4.1	480 x 100
CD4	Starvalve	6 mm firtree <sup>5</sup>	460	0.55	2.7	550 x 100
DD4	Starvalve	6 mm firtree	460	0.55	2.7	550 x 100
Ε	Pin index	Yoke fitting	680	0.92	5.4	865 × 102
F	Bull nose	58" BSP (f)	1360	1.84	14.5	930 x 140
AF	Bull nose	58" BSP (f)	1360	1.84	9.9	670 x 175
HX <sup>4</sup>	Starvalve	Schrader	2300	2.70	17.4	940 × 140
G	Bull nose	<sup>5</sup> 8" BSP (f)	3400	4.60	34.5	1320 x 178
Ĩ	Pin index	Yoke fitting	6800	9.20	68.9	1520 x 229

#### NOTES

- 1. Actual contents and weights of gas may vary about the nominal figures indicated.
- This is the approximate weight of a cylinder and valve without gas but including neck ring where appropriate. Some cylinders manufactured to older standards may weigh more than this. Add the nominal weight of gas to obtain the approximate weight of a full cylinder.
- 3. The length includes the cylinder valve.
- 4. Cylinder is filled to 230 bar (max) at 15°C.
- 5. Includes Schrader.

# **FURTHER INFORMATION**

#### Expiry date

Three years from filling date

## Pharmacological particulars

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 14% oxygen at 14 kpa (105mm HG) and the arterial blood has an oxygen tension of 13 kpa (97mm Hg). The difference known as the alveolar-arterial oxygen tension gradient, increases with age. The difference may be as great as 4kpa (30mm Hg) in a healthy, elderly individual.

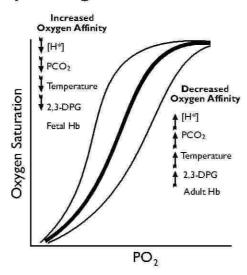
Oxygen in the blood is mostly combined with haemoglobin. Normally haemaglobin in arterial blood is 97% saturated and the oxygen content of the blood is 19.8 vol %, 0.3ml of this being carried in solution. The remainder is held in chemical combination with haemoglobin.

The average healthy individual with a basal oxygen consumption has no more than 4 minutes supply of oxygen in the blood.

#### Pharmacokinetic particulars

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 2kpa (15mm Hg), the oxygen carried in the blood from the lungs can be readily given up to the tissues.

## Oxyhaemoglobin Dissociation Curve



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.

## PRODUCT LICENCE NUMBER

PL0735/5000

## DATE OF PREPARATION

February 2002 (Revision 2)



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# Safe handling and storage of medical gas cylinders

#### General

- All personnel handling gas cylinders and responsible for pipeline gas supplies should have adequate knowledge of the properties of the gas, precautions to be taken, actions in the event of an emergency and the correct operating procedures for their installations.
- If you own your cylinders you must be aware of, and discharge your statutory obligations with regard to maintenance and testing.
- You should ensure that when cylinders are collected the driver has been properly instructed in the method of handling cylinders and in dealing with any emergency.

#### Storage of cylinders

- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- 2. 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 within the store.
- 6. Full and empty cylinders should be stored separately. Full cylinders should be used in strict rotation.
- Medical cylinders should be stored separately from industrial and other non-medical cylinders.
- 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.

#### Preparation for use

- Cylinder valves should be opened momentarily prior to use to blow any grit or foreign matter out of the outlet.
- 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.
- Only the appropriate regulator should be used for the particular gas concerned.
- Pipelines for medical gases should be installed in accordance with the conditions set out in HTM 2022.
- Cylinder valves and any associated equipment must never be lubricated and must be kept free from oil and grease.

#### Leaks

- Should leaks occur this will usually be evident by a hissing noise.
- Leaks can be found by brushing the suspected area with an approved leak test solution such as 1% \*Teepol HB7 solution.
- The gland packing around the valve spindle may become loose and can be cured by tightening the gland nut clockwise. Do not overtighten.
- Sealing or jointing compounds must never be used to cure a leak.
- Never use excessive force when connecting equipment to cylinders.

#### Use of cylinders

- 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.
- When in use cylinders should be firmly secured to a suitable cylinder support.
- Cylinders containing liquefiable gas must always be used vertically with the valve uppermost.
- 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.
- After use cylinder valves should be closed using moderate force only and the pressure in the regulator or tailpipe released.
- 8. When empty the cylinder valve must be closed.
- Ensure the plastic valve cap is refitted to bullnose valves/outlets.
- Immediately return empty cylinders to the empty cylinder store for return to BOC.

Further information concerning specific problems arising from the storage and handling of gases, hazards and first aid treatment can be obtained from BOC.

#### General references

'Gas Safe - with Medical Gases.

'Safe Under Pressure' BOC Limited.

Handbook of Compressed Gases, Compressed Gas Association Inc., Reinhold (1990).

Gas Data Book, Matheson Gas Products (1971).

The Road Traffic (Carriage of Dangerous Substances in Packages etc) Regulations 1986, SI.1986, No 1951 and supporting Code of Practice.

#### SAFETY DATA SHEET

Identification of the substance/preparation and of the company

MSDS Nr 097A Product name Oxygen Chemical Formula 02 see page 5 0645-645555 Company identification Emergency phone number

2. Composition/information on ingredients

Substance/Preparation Substance

Contains no other components or impurities which will Components/Impurities

influence the classification of the product.

CAS Nr 07782-44-7 EEC Nr (from EINESC) 2319569

3. Hazards identification

Hazards identification Compressed gas.

Oxidant. Strongly supports combustion. May react violently

with combustible materials.

4. First aid measures

Inhalation Continuous inhalation of concentrations higher than 75% may

cause nausea, dizziness, respiratory difficulty and convulsion.

5. Fire fighting measures

Specific hazards Supports combustion.

Exposure to fire may cause containers to rupture/explode.

Non flammable.

Hazardous combustion products None

Suitable extinguishing media All known extinguishants can be used. nitric oxide/nitrogen dioxide Specific methods

If possible, stop flow of product.

Move container away or cool with water from

a protected position.

Special protective equipment for fire fighters

6. Accidental release measures

Environmental precautions

Personal precautions Evacuate area. Ensure adequate ventilation.

Ensure adequate air ventilation.

Ventilate area.

Eliminate ignition sources.

Try to stop release.

Prevent from entering sewers, basements and workpits, or

any place where its accumulation can be dangerous.

Ventilate area

Clean up methods 7. handling and storage

> Handling and storage Use no oil or grease.

Open valve slowly to avoid pressure shock.

Segregate from flammable gases and other flammable

materials in store.

Suck back of water into the container must be prevented.

Do not allow backfeed into the container.

Use only properly specified equipment which is suitable

for this product, its supply pressure and temperature. Contact your gas supplier if in doubt.

Keep away from ignition sources (including static discharges).

Refer to supplier's container handling instructions. Keep container below 50°C in a well ventilated place.

8. Exposure controls/personal protection

Do not smoke while handling product. Personal protection

Wear suitable hand, body and head protection. Wear goggles

with suitable filter lenses when use is cutting/welding.

Avoid oxygen rich (>21%) atmospheres.

Ensure adequate ventilation.

No odour warning properties

9. Physical and chemical properties

Molecular weight Melting point -219°C -183°C **Boiling** point -118°C Critical temperature Relative density, gas 1.1 (air=1) Relative density, liquid 1.1 (water=1) Vapour pressure 20°C Not applicable Solubility mg/I water 39mg/1 Appearance/Colour Odour Colourless gas

Autoignition temperature

Not applicable Flammability range Oxidiser Other data

Gas/vapour heavier than air. May accumulate in confined spaces, particularly at or below ground level.

#### 10. Stability and reactivity

Stability and reactivity

May react violently with combustible materials May react violently with reducing agents. Violently oxidises organic material.

#### 11. Toxicological information

General

See page 3

#### 12. Ecological information

General

No known ecological damage caused by this product.

#### 13. Disposal considerations

General

To atmosphere in a well ventilated place. Do not discharge into any place where its accumulation

could be dangerous.

Contact supplier if guidance is required.

#### 14. Transport information

UN Nr Class/Div Subsidiary risk ADR/RID Item Nr ADR/RID Hazard Nr Tremcard Nr Labelling ADR

Other transport information

ling ADR

1072 2.2 5.1

2,1a 25 842

Label 2: non flammable non toxic gas.

Label 05: fire intensifying risk.

Avoid transport on vehicles where the load space is not separated from the driver's compartment.

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

Before transporting product containers ensure that they are firmly secured and:

- cylinder valve is closed and not leaking.

 valve outlet cap nut or plug (where provided) is correctly fitted.

 valve protection device (where provided) is correctly fitted.

adequaté ventilation.

- compliance with applicable regulations.

#### 15. Regulatory information

Number in Annex 1 of Dir 67/548 EC Classification

-Symbols -R Phrases -S Phrases

Labelling of cylinders

-Symbols

Not included in Annex 1. Proposed by the industry

0;R8A. O 8A 9,17A

Road transport symbols are used and selected according

to the most stringent product classification -

EC or ADR

Label 2: non flammable non toxic gas. Label 05: fire intensifying risk. R8A Strongly supports combustion. S9 Keep container in well ventilated place.

\$17A Keep away from combustible material, use no oil or

grease.

Risk phrases Safety phrases

#### 16. Other information

Ensure all national/local regulations are observed.

Ensure operators understand the hazard of oxygen enrichment.

Before using this product in any new process or experiment, a thorough material compatibility and safety study should be carried out. Details given in this document are believed to be correct at the time of going to press. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use can be accepted.