
PRODUCT INFORMATION

NAME OF THE MEDICINE

MEDICAL OXYGEN and MEDICAL OXYGEN (LIQUID)

Oxygen:

Chemical structure: $O = O$

CAS No.: 7782-44-7

Molecular weight: 32

DESCRIPTION

Oxygen is a colourless, odourless gas with a boiling point of -183.1°C (at 101.325 kPa) and a density of 1.355 kg/m^3 (at 15°C and 101.325 kPa).

Oxygen is present in the atmosphere at 21% and is an absolute necessity for life.

Excipients: None.

PHARMACOLOGY

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 40 and 15 mm 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.

INDICATIONS

Hypoxia of any cause.

As diluent for gaseous and volatile anaesthetic agents.

CONTRAINDICATIONS

None.

PRECAUTIONS

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

Liquid Oxygen can lead to severe “cold burns” or destruction of tissue.

Effects on fertility

Not applicable.

Use in pregnancy

Oxygen does not adversely affect pregnancy.

Category A*: when oxygen is used in pregnancy as clinically required, to treat intercurrent illness and avoid hypoxia, at the lowest concentration for the shortest possible time.

*Note: Category A definition: Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Hyperbaric oxygen treatment during gestation in mice, rats, hamsters and rabbits led to increased resorptions and foetal abnormalities, and decreased foetal body weights.

Category A does not relate to hyperbaric oxygen treatment and specialist literature should be consulted.

Use in lactation

Oxygen does not adversely affect lactation.

Paediatric use

Not applicable

Use in the elderly

Not applicable.

Genotoxicity

Not applicable.

Carcinogenicity

Not applicable.

Effect on laboratory tests

Not applicable.

INTERACTIONS WITH OTHER MEDICINES

None.

ADVERSE EFFECTS

Patients may experience retrosternal soreness associated with coughing and breathing difficulties after breathing pure oxygen at atmospheric pressure for several hours. This retrosternal soreness is exacerbated by smoking and exposure to cold air.

Convulsions and other central nervous system (CNS) effects may occur at two atmospheres or more, after a few hours exposure to pure oxygen. At higher pressures more rapid onset of CNS symptoms will occur.

Retrolental fibroplasia may occur in premature infants exposed to oxygen at concentrations greater than 40%.

DOSAGE AND 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 **ADVERSE EFFECTS**).

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%.

OVERDOSAGE

At two or more atmospheres pressure users may experience central nervous system toxicity including dizziness, convulsions and loss of consciousness after only 2-3 hours of exposure to pure oxygen.

Oxygen intake should be reduced or preferably stopped for a period of time and the effects will be reversed. Oxygen therapy can be restarted if desired.

PRESENTATION AND STORAGE CONDITIONS

Gaseous Medical Oxygen is supplied in gas cylinders with a pin index valve suitable for the filling pressure applied for the product. Size C cylinders may also be supplied with an alternative Integrated Regulator valve.

The cylinders for Gaseous Medical Oxygen may be constructed of either steel or aluminium.

Liquid Medical Oxygen (cryogenic liquid), is supplied for storage and transport purposes in bulk containers:- flasks, tanks/tankers/seatainers.

The flasks, tanks/tankers/seatainers used for Liquid Medical Oxygen are made of steel and are vacuum insulated suitable for the cryogenic nature of the content and fitted with withdrawal valves.

The types of cylinders normally used are specified in the following table (note: water capacity is nominal):

Cylinder Size	Water Volume (litres)	Maximum Fill Pressure (bar)	Fill Volume (m ³)
B	1.4	200	0.283
C	2.8	200	0.257 - 0.687
D	9.5	200	1.9
E	23	200	3.45 - 4.3
G	50	200	10
6 Pack*	300	200	60
12 Pack**	600	200	120
Flask	120-400	N/A	N/A
tanks/tankers/ seatainers	1,500 - 60,000	N/A	N/A

* 6 Packs (bundles) of 6 x 50 L Size G cylinders

** 12 Packs (bundles) of 12 x 50 L Size G cylinders

Notes:

Cylinders, cylinder labelling, colour coding and cylinder valves all comply with the relevant Australian Standards.

The colour code for Medical Oxygen cylinders is a white body with a white shoulder.

Instruction for Use/Handling

Care is needed in the handling and use of **Medical Oxygen** gas cylinders. Refer to the respective S.D.S and the “caution” section of the product label. For Liquid Medical Oxygen, the extreme cold can lead to “cold burns”/ destruction of tissue.

Preparation for use with Pin Index Valves

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

Preparation for use with Integrated Regulator Valves

1. Connect oxygen tubing to “fir tree” outlet on top of the integrated regulator valve.
2. Connect oxygen equipment to sleeve index on the side of the integrated valve regulator.
3. Open the integrated regulator valve slowly.
4. Select desired flow rate on top of integrated regulator valve.

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 appropriately and return them to Coregas 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.

Handling of 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 liquefiable 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 empty the cylinder valve must be closed.
9. Immediately return empty cylinders to the empty cylinder store for return to Coregas.

Storage

Storage should be according to the appropriate Australian Standards.

Cylinders should be kept out of the reach of children.

Oxygen is enhancing combustion (including some materials which do not normally burn in air). High pressure Oxygen can lead to oxidation / fire / explosion when getting in contact with oils, greases, tarry substances and many plastics (spontaneous combustion).

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 empty 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.
- D size cylinders and larger should be stored vertically. C size cylinders can be stored horizontally.
- Precautions should be taken to protect cylinders from theft.

In addition to the above, for Liquid Oxygen:

Personal Protective Equipment in the form of a face shield, long shirts / trousers or overalls, isolated gauntlets and safety boots must be worn.

NAME AND ADDRESS OF THE SPONSOR

Coregas Pty Ltd
66 Loftus Road
Yennora NSW 2161
Australia

POISON SCHEDULE OF THE MEDICINE

Unscheduled.

Date of first inclusion in the Australian Register of Therapeutic Goods:

Medical Oxygen: 02/01/1992

Medical Oxygen (liquid): 17/01/2013

Date of most recent amendment: 20 March 2015

Medical Oxygen AUST R: 34472.

Medical Oxygen (liquid) AUST R: 199515