

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Oxygen/Carbon Dioxide mixtures

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Medical Oxygen/ Carbon Dioxide Mixtures cylinders are supplied to the following specifications:

Chemical Composition: Oxygen 95.0% +/- 0.5%
Carbon Dioxide 5.0% +/-0.5%

The specification above is the most commonly used mixture. There are various other mixtures as follows:

Oxygen 98% Carbon Dioxide 2%
Oxygen 97% Carbon Dioxide 3%
Oxygen 90% Carbon Dioxide 10%
Oxygen 80% Carbon Dioxide 20%

The Medical Oxygen specification complies with the current European Pharmacopoeia monograph (0417) and the Carbon Dioxide specification complies with the current European Pharmacopoeia monograph (0375)

3 PHARMACEUTICAL FORM

Medicinal gas, compressed.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

1. In blood gas analysis.
2. For use in the oxygenator during extracorporeal circulation.

4.2 Posology and method of administration

Posology
As appropriate.

Paediatric population
Currently available data are described in section 4.8 but no recommendation on posology can be made.

Method of administration
As appropriate.

4.3 Contraindications

Not applicable.

4.4 Special warnings and precautions for use

The product should be used under the direction of appropriately trained personnel.

Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of additional oxygen such as within Medical Oxygen/Carbon Dioxide mixtures should be avoided.

4.5 Interaction with other medicinal products and other forms of interactions

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 Medical Oxygen/Carbon dioxide mixtures should be administered with caution and at levels kept as low as possible.

4.6 Fertility, pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

Not applicable.

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

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Medical Gas, ATC Code: VO3AN02, VO3AN01

The characteristics of oxygen are:-

Odourless, colourless gas.

Molecular weight: 32.00

Boiling point: -183.1 °C (at 1bar)

Density: 1.335kg/m³ (at 15 °C)

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

The characteristics of Carbon Dioxide are:-

Odourless, colourless gas.
 Modular weight: 44.00
 Boiling point: - 78.5 ° C (at 1bar)
 Density: 1.872kg/m³ (at 15 ° C)

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Whereas Oxygen vigorously support combustion, Carbon Dioxide is an asphyxiant at high concentration.

Oxygen/Carbon Dioxide mixtures should be treated as Oxygen. 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.

Oxygen/Carbon Dioxide medical gas mixtures should not be used with adrenergic substances such as adrenaline.

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Medical Oxygen/Carbon Dioxide Gas Mixture 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

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 Medical Oxygen/Carbon Dioxide Gas Mixture cylinders.

6.5 Nature and contents of container

A summary of Medical Oxygen/Carbon Dioxide Gas Mixture cylinders, their size and construction and type of valve fitted are detailed below:

Cylinder Size	Gas Content Litres	Cylinder Construction	Valve Outlet	Valve Construction
F	1360	Steel	BS 341 No.3 Top outlet MPR valve	Brass
G	3400	Steel	BS 341 No. 3 Top outlet MPR valve	Brass

J	6800	Steel	BS 341 No. 3 Top outlet MPR valve	Brass
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Cylinders

All cylinders used for the supply of Medical Oxygen/Carbon Dioxide Gas Mixtures are manufactured from high tensile steel and designed with a working pressure of at least 137 bar (g). The cylinders have a black body with a grey and white quartered shoulder.

Cylinder Valves

Medical Oxygen/Carbon Dioxide Gas Mixture cylinders are fitted with valves with outlet connections that conform to BS 341 (5/8 BSP F). The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 6.6 insert. These cylinders are designed to be used with an additional pressure regulator.

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/Carbon Dioxide Gas Mixture 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

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.
- ensure the batch label fitted to the cylinder is not removed or discarded
- ensure that an appropriate 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 leaks.

Leaks

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

Use of Cylinders

When Medical Oxygen/Carbon Dioxide Gas Mixture 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 Medical Oxygen/Carbon Dioxide Gas Mixture 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
- empty cylinders are immediately returned to an empty cylinder storage area for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Gases Ireland Ltd
Bluebell
Dublin
12
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0208/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 September 1985

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

February 2020

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable