

Medical oxygen/carbon dioxide mixtures



Summary of Product Characteristics (SPC)

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

4.2 Posology and 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.

4.5 Interaction with other medicinal products and other forms of interaction
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.

4.6 Pregnancy and lactation
Not applicable.

4.7 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
Not applicable.

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

5. Pharmacological properties
Pharmacotherapeutic Group – Medical Gas
ATC Code – VO3AN02, VO3AN01

5.1 Pharmacodynamic properties
The characteristics of Oxygen are:

- Odourless, colourless gas
- Modular weight 32.00
- Boiling point -183.1°C (at 1 bar)
- Density 1.335 kg/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 1 bar)
- Density 1.872 kg/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 1 year.

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

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 Instructions for Use/Handling

General

All personnel handling Medical Oxygen/Carbon Dioxide Gas Mixture cylinders should have adequate knowledge:

- 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 Limited
J F Kennedy Drive
Bluebell
Dublin 12

8. Marketing authorisation number(s)

PA 208/4/1

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation: 27/09/1985.
Date of last renewal: 01/04/2010.

10. Date of revision of the text

September 2016.

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Additional Safety Information

1. Contact information BOC telephone number to be used in the event of an emergency
ROI 1890 355 255

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 preparations 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

- No smoking or naked flames near medical gas mixture 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.

5% carbon dioxide/oxygen medical gas mixture 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).

5% carbon dioxide/oxygen medical gas mixture 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.

The UK exposure limit for carbon dioxide (as defined in EH40/2005) specifies:

- the Long Term Exposure Limit (LTel) (Time Weighted Average (TWA) over 8 hours) is 5000ppm
- the Short Term Exposure Limit (STel) (measured over a 15 minute period) is 15000pm.

3. Fire fighting measures If 5% carbon dioxide/oxygen medical gas mixture cylinders are involved in a fire:

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

All types of fire extinguishers may be used when dealing with a fire involving 5% carbon dioxide/oxygen medical gas mixture cylinders.

Fire fighters should use self-contained breathing apparatus when dealing with a fire involving 5% carbon dioxide/oxygen medical gas mixture cylinders within a confined space.

If clothing becomes impregnated with this mixture (due to a leak), keep away from sources of ignition or open flames. Clothing impregnated with this mixture should be ventilated in fresh air for a minimum of 15 minutes.

There are no hazardous combustion products released from the gas.

4. Accidental release measures If a large volume of 5% carbon dioxide/oxygen medical gas mixture is released, if it is safe to do so, you should:

- close cylinder valve
- where possible, eliminate 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 required to be used if this mixture is released in a confined area.

If clothing becomes impregnated with this mixture (due to a leak), keep away from sources of ignition or open flames. Clothing impregnated with this mixture should be ventilated in fresh air for a minimum of 15 minutes.

5. Exposure controls When using 5% carbon dioxide/oxygen medical gas mixture cylinders ensure adequate ventilation.

6. Disposal considerations It is recommended that 5% carbon dioxide/oxygen medical gas mixture 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 5% carbon dioxide/oxygen medical gas mixture 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. Transport information

UN number	UN3156
Proper shipping name	Compressed gas, oxidizing, N.O.S. (oxygen, carbon dioxide)
Material	Class 2
Labels	2.2, 5.1
Hazard identification number	25
Emergency Action Code	25
Tunnel Restriction Code	E
Transport category	3

BOC Healthcare

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