BOC
A Member of The Linde Group

10% carbon dioxide/oxygen medical gas mixture.

Essential safety information.

BOC: Living healthcare

10% carbon dioxide/oxygen medical gas mixture SPC

1. Name of the medicinal product

10% carbon dioxide/oxygen medical gas mixture

2. Qualitative and quantitative composition

10% carbon dioxide/oxygen medical gas mixture is a medicinal gas mixture of carbon dioxide and oxygen.

The mixture specification is as follows:

carbon dioxide	10.0% +/-0.5%
oxygen	balance.

The medical oxygen specification complies with the current European Pharmacopoeia monograph (0417) and the carbon dioxide specification complies with the European Pharmacopoeia monograph (0375).

3. Pharmaceutical form

Medicinal gas, compressed.

4. Clinical particulars

4.1 Therapeutic indications

The need for pre-determined gas mixtures of carbon dioxide and oxygen has been sharply reduced in recent years. The most common use of 10% carbon dioxide/oxygen medical gas mixture is for physiological investigations.

4.2 Posology and method of administration

10% carbon dioxide/oxygen medical gas mixture is administered by inhalation through the lungs usually for a fixed period.

4.3 Contraindications

There are no contraindications for the use of 10% carbon dioxide/oxygen medical gas mixture in any age group.

The duration and circumstances of the exposure to 10% carbon dioxide/oxygen medical gas mixture is always at the discretion of the attendant physician who makes the decision in the light of the particular circumstances.

4.4 Special warnings and precautions for use

Administration of 10% carbon dioxide/oxygen medical gas mixture to patients with chronic respiratory disease or drug induced respiratory depression is potentially dangerous. It should not be given to acidotic patients. Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of gases containing more than 21% oxygen should be avoided.

10% carbon dioxide/oxygen medical gas mixture is non flammable but strongly supports combustion and should not be used near sources of ignition. Smoking should be prohibited when using 10% carbon dioxide / oxygen medical gas mixture.

Under no circumstances should oils or grease be used to lubricate any part of the 10% carbon dioxide/ oxygen medical gas mixture cylinder or the associated equipment used to deliver the gas to the patient.

Where moisturising creams are required for use with a facemask or in nasal passages, oil based creams should not be used.

Check that hands are clean and free from any oils or grease. Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling 10% carbon dioxide /oxygen medical gas mixture cylinders or equipment.

4.5 Interaction with other medicinal products and other forms of interaction

10% carbon dioxide/oxygen medical gas mixture will interact with anaesthetic agents when the concentration is raised and gives rise to cardiac dysrhythmias. The threshold for dysrhythmias varies with different drugs.

By altering pH, the use of 10% carbon dioxide/oxygen medical gas mixture influences the uptake and distribution by many drugs, including neuromuscular blocking agents and hypotensive agents.

10% carbon dioxide/oxygen medical gas mixture will interact with adrenergic substances such as adrenaline. They should not be used together.

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 Pregnancy and lactation

10% carbon dioxide/oxygen medical gas mixture is not contraindicated in pregnancy and is unlikely to influence lactation.

4.7 Effects on ability to drive and use machines

The inhalation of 10% carbon dioxide/oxygen medical gas mixture should be directly supervised by a clinician so that the question of driving or controlling machinery should not arise.

4.8 Undesirable effects

The use of 10% carbon dioxide/oxygen medical gas mixture may produce sweating, nausea and headache in a small number of patients.

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 The Yellow Card System www.mhra.gov.uk/yellowcard

4.9 Overdose

No overdose effects are seen with 10% carbon dioxide/oxygen medical gas mixture but its use needs careful supervision.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group – medical gas.
ATC code: V03AN02, V03AN01.

10% carbon dioxide/oxygen medical gas mixture consists of 10% carbon dioxide with the balance being oxygen. The pharmacological particulars of the constituent gases are as follows:

Carbon dioxide – The characteristics of carbon dioxide are:
- odourless, colourless gas
- molecular weight 44
- sublimation point -78.5°C (at 1bar(g))
- density 1.872kg/m3 (at 15°C).

The effect of inhaling carbon dioxide, or of its accumulation in the body through ventilation defects, varies with the tension achieved in the blood, the duration and condition of the exposure and the susceptibility of the individual concerned.

Oxygen - The characteristics of oxygen are:
- odourless, colourless gas
- molecular weight 32
- boiling point -183.1°C (at 1bar(g))
- density 1.355kg/m3 (at 15°C).

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

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If a normal conscious patient inhales 10% carbon dioxide/oxygen medical gas mixture, the rate and depth of breathing rise and the minute volume increases. The skin becomes warm and pink and there may be sweating and a sense of discomfort.

Dizziness may develop and some patients may become unconscious.

However, when the subject returns to breathing in air, an "off-effect" is commonly seen with malaise, pallor, headache and occasional nausea and vomiting, probably due to metabolic effect induced by inhaling a volatile acid.

5.2 Pharmacokinetic properties

When 10% carbon dioxide/oxygen medical gas mixture is inhaled, absorption from the lungs into the blood is rapid and a new equilibrium between the concentration in alveolar air and that in the blood is soon established. The gas is carried partly in solution in the plasma, but mostly either as bicarbonate or as carbamino compound.

The relative quantities in solution and as bicarbonate regulate the reaction of the blood and buffer any change in pH produced by stronger organic acids. The blood concentration of carbon dioxide is set at a higher level and the excretion of the gas is adjusted to maintain the new equilibrium by increasing output.

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

None

6.2 Incompatibilities

The constituent gases of 10% carbon dioxide/oxygen medical gas mixture are chemically inactive and will not normally react with other compounds at normal temperatures.

However the compressed medical oxygen component of 10% carbon dioxide/ oxygen medical gas mixture strongly supports combustion and will cause substances to burn, including some materials that will 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 compressed medical oxygen in relatively high concentrations.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

10% carbon dioxide/oxygen medical 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 10% carbon dioxide/oxygen medical gas mixture cylinders.

6.5 Nature and contents of container

10% carbon dioxide/oxygen medical gas mixture is supplied in high pressure gas cylinders filled to 137bar(g). Conventional high pressure cylinder valves with side outlets that conform to BS 341 (5/8" BSP F), are fitted to all 10% carbon dioxide/ oxygen medical gas mixture cylinders. These cylinders are designed to be used with a pressure regulator.

Cylinder and valve details

A summary of 10% carbon dioxide/oxygen medical gas mixture cylinders, their size and construction and type of valve fitted are detailed below:

Cylinder details			Valve details		
Size	Gas content (litres)	Cylinder construction	Valve outlet	Valve construction	Cylinder Pressure bar(g)
AV	1,370	Aluminium	BS 341 No.3 Side outlet Handwheel valve	Brass	137
L	6,850	Steel	BS 341 No.3 Side outlet Handwheel valve	Brass	137

The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a nylon 6.6 insert

6.6 Special precautions for disposal and other handling

All personnel handling 10% carbon dioxide/oxygen medical 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 cap, where fitted, 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 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
- ensure that the cylinder valves and any associated equipment is not lubricated and kept free from oil and grease
- 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 10% carbon dioxide/oxygen medical 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 10% carbon dioxide/oxygen medical gas mixture cylinders are empty ensure that the:

- cylinder valves are 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 Ltd, The Priestley Centre, 10 Priestley Road, The Surrey Research Park,Guildford, Surrey GU2 7XY.

8. Marketing authorisation number(s)

PL 0735/0014R.

9. Date of first authorisation/renewal of the authorisation

Date first granted: 01/09/1972.

Date of renewal: 27/03/1991.

10. Date of revision of the text

25/05/2016

11. Dosimetry (if applicable)

Not applicable.

12. Instructions for preparation of radiopharmaceuticals (if applicable)

Not applicable.

Notes

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 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

10% 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).

10% 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 10% 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 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 10% carbon dioxide/oxygen medical gas mixture cylinders.

Fire fighters should use self-contained breathing apparatus when dealing with a fire involving 10% 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 10% carbon dioxide/oxygen medical gas mixture is released, if it is safe to do so, you should:
- close the 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 10% carbon dioxide/oxygen medical gas mixture cylinders ensure adequate ventilation.

6. Disposal considerations

It is recommended that 10% 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 10% 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	2S
Tunnel Restriction Code	E
Transport category	3

Notes

Notes

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