

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medical Carbon Dioxide.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Medical Carbon Dioxide cylinders are supplied to the following specification:
Carbon Dioxide Purity 99.5% v/v min

The Medical Carbon Dioxide cylinder specification complies with the current European Pharmacopeia monograph (0375)

3 PHARMACEUTICAL FORM

Medicinal gas, liquefied.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Medical Carbon Dioxide is used:

- (a) in gynaecological investigation for insufflation into fallopian tubes and abdominal cavities.
- (b) to restart spontaneous respiration after a period of properly controlled respiration, which is usually maintained in part by moderate hyper ventilation with temporary hypocapnia.
- (c) as solid carbon dioxide (dry ice) in tissue freezing techniques and for the destruction of warts by freezing.

4.2 Posology and method of administration

Carbon Dioxide should only be given under the direct supervision of an appropriately qualified clinician.

Carbon dioxide may be insufflated into the abdominal cavity in small increments as appropriate to distend it to allow the investigation and treatment of intra-abdominal disease, particularly of a gynaecological nature.

To restart spontaneous respiration, carbon dioxide is administered through the lungs by inhalation, with an appropriate concentration of oxygen.

Carbon dioxide snow should be applied to the affected area for 4-5 seconds.

4.3 Contraindications

Carbon Dioxide is contra – indicated: in acidosis.

4.4 Special warnings and precautions for use

Carbon Dioxide is stored in high pressure gas cylinders as a liquid under pressure. Rapid opening of the valve can cause the discharged gas to re-liquefy. This liquid can cause cold burns if in contact with the skin. Cylinders should only be used in the vertical position with the valve uppermost.

Care is needed in the handling and use of carbon dioxide gas cylinders.

Smoking should be prohibited when using Carbon Dioxide.

Under no circumstances should oils or grease be used to lubricate any part of the Carbon Dioxide 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 Carbon Dioxide cylinders or equipment.

4.5 Interaction with other medicinal products and other forms of interaction

When this agent is used for peritoneal insufflation during laparoscopy it is essential that adequate oxygenation is provided, together with removal of carbon dioxide, preferably through I.P.P.V.

Carbon Dioxide interacts with anaesthetic agents when the concentration is raised and give rise to cardiac dysrhythmias. The threshold for dysrhythmias varies with different anaesthetic agents.

Carbon Dioxide, by altering pH, influences uptake distribution and action of many drugs including neuromuscular blocking agents, and hypotensive agents.

Carbon Dioxide interacts with adrenergic substances such as adrenaline. They should not be used together.

4.6 Fertility, pregnancy and lactation

The use of carbon dioxide is not recommended in pregnancy but is unlikely to influence lactation.

4.7 Effects on ability to drive and use machines

Inhalation of carbon dioxide is not compatible with driving or use of machinery.

4.8 Undesirable effects

Carbon dioxide may produce unconsciousness in concentrations over 10%. Cardia dysrhythmias have been reported in patients undergoing laparoscopy as a result of high blood carbon dioxide levels. Cardiac arrest due to gas embolism has been reported.

When solid carbon dioxide is used to treat warts etc, it is essential that the surrounding tissue is not touched since it will be damaged.

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: <http://www.hpra.ie/>

E-mail: medsafety@hpra.ie

4.9 Overdose

Moderate overdose of carbon dioxide less than 5 per cent stimulates breathing. If excessive this may cause extreme respiratory difficulty, raise the blood pressure and lead to nausea and vomiting and occasionally unconsciousness. In concentration above 10 per cent, carbon dioxide possesses anaesthetic properties.

Overdose may necessitate assisted or controlled ventilation with an appropriate oxygen concentration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Medical Gas

ATC Code: V03AN02

The characteristics of carbon dioxide are:

- Odourless, colourless gas.
- Molecular weight 44.01
- Sublimation point -78.5°C (at 1 bar)
- Density 1.872kg/M3 (at 15°C)

Carbon Dioxide occurs at approximately 350vpm in the atmosphere.

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

If a normal, conscious individual inhales 5% carbon dioxide, the rate and depth of breathing rise and the minute volume increases 2 to 5 fold. The skin becomes pink and warm and there may be some sweating and a sense of discomfort. There is no effect on consciousness or mental function, even with long exposures. After a prolonged exposure, when the return to breathing air takes place, an "off effect" may develop with malaise, pallor, headache and occasional nausea and vomiting, probably due to the metabolic disturbances as a result of breathing a volatile acid.

If the inspired concentration is raised further, these effects become exaggerated in proportion to the concentration. At around 8-9% dizziness may develop, and at 10% some subjects become unconscious. Most people will become unconscious at 12.5% and all subject lose consciousness within 1-2 minutes at 20%.

When the concentration is raised to 30%, consciousness is lost rapidly, the blood pressure may rise to 27kpa (200mm Hg) or higher and there is intense vasoconstriction, a reduction in heart rate to 40-50 beats per minute and ECG changes. All anaesthetic agents reduce these responses to carbon dioxide.

5.2 Pharmacokinetic properties

When inhaled, carbon dioxide is rapidly distributed throughout the body.

Physiologically, it regulates the rate and depth of breathing and normally there is constant tension of 5kpa (40mm Hg) in arterial blood.

The concentration of carbon dioxide in the plasma is three times greater than that in red blood cells. The gas is carried in solution (2.4-2.7 vol%), but mostly either as bicarbonate (42.9 – 46.7 vol %) or as carbamino compound (3.0 – 3.7 vol%). The relative quantities in solution and as bicarbonate regulate the reaction of the blood and buffer changes in pH produced by stronger organic acids.

Carbon Dioxide produced by metabolism plays an integral part in the supply of oxygen to the tissues, since the amount released by haemoglobin at any given oxygen tension is directly related to the carbon dioxide tension in the blood. This in turn is governed by tissue activity and the concentration inhaled. Thus the rate at which oxygen is given up to

the tissues is increased when the carbon dioxide tension is raised.

When a patient becomes apnoeic, carbon dioxide produced in the tissues, accumulates in the blood at a rate of about 0.7kpa (5mmHg) per minute.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Carbon dioxide should not be given when adrenaline is used.

Carbon Dioxide is highly dangerous when in contact with oils, gases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Medical Carbon Dioxide 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
- E size cylinders and smaller should be stored horizontally

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 Carbon Dioxide cylinders.

6.5 Nature and contents of container

A summary of Medical Carbon Dioxide cylinders, their size and construction, type of valve fitted and valve outlet pressure is detailed below.

Cylinder Size	Gas Content (litres)	Cylinder Water Capacity (Litres)	Cylinder Construction	Valve Construction
C	450	Steel	Pin Index	Brass
E	1800	Steel	Pin Index	Brass
VF	3600	Steel	0.860" x 14 TPI	Brass

			(M)	
LF	3600	Steel	0.860" x 14 TPI (M)	Brass

Cylinders

All cylinders used for the storage of Carbon Dioxide are manufactured from high tensile steel with a designed working pressure of at least 50 bar (g).

All cylinders require an appropriate regulator to be fitted prior to use.

The colour coding of the shoulders of Medical Carbon Dioxide is grey (RAL 7037).

The colour coding of the cylinder body is white (RAL 9010). Cylinders also carry the carbon dioxide name on the body of the cylinder.

For a limited period, cylinders may have grey bodies. These cylinders do not have the name carbon dioxide on the body of the cylinder.

The programme to convert all Medical Carbon dioxide cylinders to white bodies will be completed by 2025.

Cylinder Valves

Medical Carbon Dioxide cylinders are supplied with two main types of cylinder valves.

Medical Carbon Dioxide C and E cylinders are fitted with valves with outlet connections that conform to ISO 407 (pin index).

LF and VF size cylinders are fitted with outlet connections that conform to BS 341(Type 8) (11/16" x 20 TPI (M)) and are filled with liquid to a specified weight. The pressure in the cylinder is dependant on the vapour pressure at the cylinder temperature.

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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

All personnel handling Medical Carbon Dioxide 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.
-

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.
- 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.
- ensure that the cylinder valves and any associated equipment is not lubricated and is kept free from oil and grease.
- 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 Carbon Dioxide 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 Carbon Dioxide 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 store for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Gases Ireland Limited
J F Kennedy Drive
Bluebell
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA0208/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

September 2015

11 DOSIMETRY

Not applicable

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable