SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Carbon Dioxide

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbon Dioxide Ph. Eur. 100%

3 PHARMACEUTICAL FORM

Inhalation gas

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an anaesthetic supplement in various clinical circumstances to maintain optimum blood carbon dioxide levels, facilitate blind intubation and rapidly increase depth of anaesthesia with volatile agents. As a respiratory stimulant after apnoea or after relief of chronic respiratory obstruction. To prevent hypocapnia during hyperventilation. Use in clinical and physiological investigations including use as insufflation gas.

4.2 Posology and method of administration

Use in adults, including the elderly and children

For respiratory use at concentrations of 5% or less, except for certain investigations where concentration may exceed 5%. Also 100% carbon dioxide may be used for insufflation.

4.3 Contraindications

Carbon dioxide should not be used in acidosis, in respiratory obstruction and during resuscitation.

4.4 Special warnings and precautions for use

None

4.5 Interaction with other medicinal products and other forms of interaction

Carbon dioxide interacts with anaesthetic agents when the concentration is raised and gives rise to cardiac dysrhythmias. It also interacts with adrenergic substances (e.g. adrenaline).

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

4.6 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

If a normal, conscious individual inhales 5% carbon dioxide, the rate and depth of breathing rise and the minute volume increases 2-5 fold. The skin becomes pink and warm and there may be 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 disturbance as a result of breathing a volatile acid.

Cardiac 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.

4.9 Overdose

At concentrations of greater than 6%, carbon dioxide causes headache, mental confusion, palpitations, hypertension, dyspnoea, increased depth and rate of respiration and depression of the central nervous system. At around 8-9% dizziness may develop. At concentrations of 10% and higher carbon dioxide possesses anaesthetic properties and may cause unconsciousness. Most people will become unconscious at 12.5% and all subjects lose consciousness with 1-2 minutes at 20%. When the concentration is raised to 30%, consciousness is lost rapidly, the blood pressure may rise to 27kPa (200mmHg) or higher and there is intense vasoconstriction, a reduction in heart rate to 40-50 beats per minute and ECG changes. Convulsions may occur. Inhalation of 50% carbon dioxide has been reported to produce central effects similar to anaesthetics. All anaesthetic agents reduce the responses to carbon dioxide.

The effects are reversed when the breathing of carbon dioxide ceases.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Carbon dioxide is a colourless odourless gas with a molecular weight of 44.01, a sublimation point of -78.5°C (at 1 bar), a specific gravity of 1.53 and a density of 1.872 kg/m^3 (at 15°C and 1013mb).

Carbon dioxide occurs at approximately 350ppm v/v in the atmosphere.

Carbon dioxide is a potent stimulus to respiration. Carbon dioxide has circulatory effects and increases heart rate and cardiac output. Carbon dioxide also causes depression of cerebral cortex activity.

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 (see 4.9)

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 (40 mmHg) 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 partly 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 the tissues, accumulates in the blood at a rate of about 0.7 kPa (5mmHg) per minute.

5.3 Preclinical safety data

There are no additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

There are no incompatibilities with carbon dioxide

6.3 Shelf life

Five years

6.4 Special precautions for storage

Cylinders should be kept out of the reach of children.

Carbon dioxide is non-flammable and does not support 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 used 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.
- F size cylinders and larger should be stored vertically E size cylinders and smaller should be stored horizontally.
- Precautions should be taken to protect cylinders from theft.

6.5. Nature and Contents of Container

Carbon dioxide is supplied in a gas cylinder with valve, suitable for the pressure required for the product.

The types of cylinders normally used are specified in the following table.

Cylinder Size	Water Volume (litres)	Fill Pressure (bar)	Fill Volume (m^3)	Valve Type [1]
C	1.2	57.2	0.45	Pin-index
E	4.68	57.2	1.8	Pin-index
LF	9.43	57.2	3.6	BS No.8 0.860" x 14 TPI male (DIP)
VF	9.43	57.2	3.6	BS No.8 0.860" x 14 TPI male

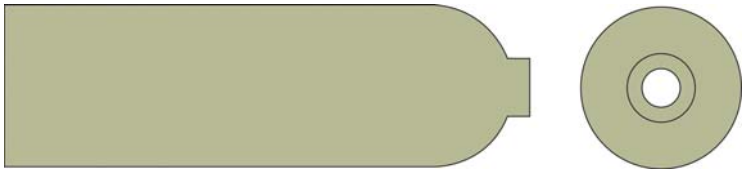
Note: (1) Cylinder valves conform to BS341 (non pin-index) and BS EN ISO 407 (pin-index)

The colour of Medical Carbon Dioxide cylinders in the UK is in a period of change.

The colour coding of the shoulder of Carbon Dioxide is French grey. The body of the cylinder will be either French grey or white.

The aim is to complete a period of change over from the French grey body to the white bodied cylinder. The shoulder colour of the cylinder will remain as French grey. This period of change will be completed by January 1st 2026. The images below represent the new and current colour coding of Medical Carbon Dioxide cylinders:

New white bodies Medical Carbon Dioxide cylinder colour coding



Current Medical Carbon Dioxide cylinder colour coding

6.6 Special precautions for disposal

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.

Preparation for use

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 '0' 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.
6. Pipelines for medical gases should be installed in accordance with the conditions set out in HTM 2022

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, and return them to Linde Gas 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.

Use 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 only a small amount of gas remains in a cylinder, the cylinder valve must be closed. It is important to leave a small residual pressure in each cylinder after use, in order to protect the inside of the cylinder from contamination.
9. Immediately return used cylinders to the used cylinder store for return to Linde Gas.

7 MARKETING AUTHORISATION HOLDER

Air Liquide Limited
Station Road
Coleshill
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B46 1JY

8 MARKETING AUTHORISATION NUMBER

PL 15929/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/02/1998 / 16/04/2003

10 DATE OF REVISION OF THE TEXT

17/07/2012