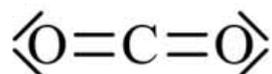


PRODUCT INFORMATION

NAME OF THE MEDICINE

MEDICAL CARBON DIOXIDE 100% v/v Carbon Dioxide gas

Chemical structure:



CAS No. : 124-38-9

MW: 44.01

DESCRIPTION

Carbon Dioxide is a colourless odourless gas with a sublimation point of -78.5°C (at 101.325 kPa), a specific gravity of 1.53 (at 15°C and 101.325 kPa) and a density of 1.872 kg/m^3 (at 15°C and 101.325 kPa).

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

Excipients: None.

PHARMACOLOGY

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 **OVERDOSAGE**).

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 5 kPa (40 mm 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 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 in the tissues accumulates in the blood at a rate of about 0.7 kPa (5 mm Hg) per minute.

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.

CONTRAINDICATIONS

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

PRECAUTIONS

Carbon Dioxide is an asphyxiate, so use only in well ventilated areas.

Effects on fertility:

Not applicable

Use in pregnancy:

The use of Carbon Dioxide is not recommended in pregnancy.

Category C: Drugs which, owing to their pharmacological effects, have caused or maybe suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.

Use in lactation:

Carbon Dioxide is unlikely to influence lactation.

Paediatric use:

Not applicable.

Use in the elderly

Not applicable.

Carcinogenicity

Not applicable.

Genotoxicity

Not applicable.

Interactions with other medicines:

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.

Effect on laboratory tests

Not applicable.

Effects on Ability to Drive and Use Machines:

Inhalation of Carbon Dioxide is not compatible with driving vehicles or the use of machinery.

ADVERSE 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.

DOSAGE AND ADMINISTRATION**Use in adults, 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.

OVERDOSAGE

At concentrations of greater than 6%, Carbon Dioxide causes headaches, 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 27 kPa (200 mm Hg) 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 in of Carbon Dioxide ceases.

PRESENTATION AND STORAGE CONDITIONS

Carbon Dioxide is supplied in a gas cylinder with a PIN index valve, suitable for the filling pressure applied 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 (kg)
C	2.8	50	1.8
D	9.5	50	5.9
E	23	50	14.5
G	50	50	30

Notes:

Cylinders conform to AS 2030.1

Cylinder valves conform to AS 2473.1 and AS 2473.3

The cylinders are colour coded conforming to AS 4484.

The colour code for Medical Carbon Dioxide is a white body with a green grey shoulder (*plus 2 x "N" for "new colour code"*).

Instructions for Use/Handling

Care is needed in the handling and use of **Medical Carbon Dioxide** gas cylinders. Refer to the respective S.D.S and the "caution" section of the product label.

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 'O' 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.

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 appropriately and return them to Coregas 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.

Handling 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 empty the cylinder valve must be closed.
9. Immediately return empty cylinders to the empty cylinder store for return to Coregas.

STORAGE:

Cylinders should be kept out of the reach of children.

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 empty 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.
- All cylinders should be stored vertically.

- Precautions should be taken to protect cylinders from theft.

NAME AND ADDRESS OF THE SPONSOR

Coregas Pty Ltd
66 Loftus Road
Yennora NSW 2161
Australia

POISON SCHEDULE OF THE MEDICINE

Unscheduled.

DATE OF APPROVAL

TGA approval: 21/10/1991.

Date of first inclusion in the Australian Register of Therapeutic Goods: 21/10/1991

Date of most recent amendment: 30/05/2013

AUST R: 27190.