SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medical Carbon Dioxide 5%/Oxygen 95%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbon dioxide Ph.Eur. 5% and oxygen Ph.Eur. 95%

3 PHARMACEUTICAL FORM

Inhalation gas

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a respiratory stimulant after apnoea or after chronic respiratory obstruction has been relieved.

In clinical situations where carbon dioxide is needed as an anaesthetic supplement. Use in clinical and physiological investigations.

4.2 Posology and method of administration

Use in adults, including the elderly, and children

For respiratory use

For use in neonates:

When administering oxygen to neonates, the inspired concentration of oxygen should not exceed 40%.

4.3 Contraindications

The gas mixture is contra-indicted in acidosis, chronic respiratory disease and patients with drug-induced respiratory depression.

4.4 Special warnings and precautions for use

Oxygen supports combustion and smoking should be prohibited when this gas mixture of carbon dioxide 5% and oxygen 95% is use.

4.5 Interaction with other medicinal products and other forms of interaction

Carbon dioxide 5%/oxygen 95% interacts with anaesthetic agents when the carbon dioxide concentration is raised and gives rise to cardiac dysrhythmias. The onset of these symptoms varies with the type of anaesthetic. The mixture also interacts with adrenergic substances (e.g. adrenaline). Adrenergic substances should not be used at the same time as carbon dioxide 5%/oxygen 95%.

Carbon dioxide 5%/oxygen 95%, by altering pH, influences uptake distribution and action of many drugs including neuromuscular blocking agents, and hypotensive agents. Care should be taken when administering drug substances at the same time as carbon dioxide 5%/oxygen 95%,

4.6 Pregnancy and lactation

The gas mixture is not specifically contra-indicated in pregnancy but its use is not recommended. The gas mixture is unlikely to influence lactation.

4.7 Effects on ability to drive and use machines

The inhalation of carbon dioxide 5%/oxygen *95%* is not compatible with driving or the operating of machinery.

4.8 Undesirable effects

Use of the gas mixture may result in sweating, nausea and headache in a small number of patients.

4.9 Overdose

None

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Carbon dioxide occurs as approximately 350ppm v/v 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.

Oxygen is a colourless, odourless gas with molecular weight 32, a boiling point of -183.1°C (at 1 bar) and a density of 1.355 kg/m^3 (at 15°C and 1013mb).

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

5% carbon dioxide/95% oxygen gas mixture has a specific gravity of 1.13 (at 15°C) and a density of 1.38 kg/m^3 (at 15°C and 1013mb).

5.2 Pharmacokinetic properties

The uptake of oxygen by the blood in the lungs and discharge to the tissues is determined by the oxygen dissociation curve. The characteristic sigmoid shape ensures that, at tensions between 40 and 15 mm Hg, the oxygen carried in the blood from the lungs can be readily given up to the tissues.

The uptake from the lungs is rapid because blood flow through the capillaries, where exchange takes place, occurs in about 0.5 seconds. The uptake of oxygen is favoured by the simultaneous loss of carbon dioxide which is then excreted in the expired air. Conversely the entry of carbon dioxide into the blood from the tissues facilitates oxygen transfer to the cells.

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 5%/oxygen 95% in clinical practice.

6.3 Shelf life

Five years.

6.4 Special precautions for storage

Cylinders should be kept out of the reach of children.

Whereas oxygen vigorously supports combustion, carbon dioxide is an asphyxiant at high concentrations. The carbon dioxide/oxygen mixture 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.

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 5%/oxygen 95% 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 (m^3)**	**Fill Volume (m^3)**	**Valve Type [1]**
F	9.43	137	1.36	Bullnose 5/8 BSP female
F4	9.43	230	2.3	4 bar outlet Schraedr
G	23.6	137	3.4	connector
G4	23.6	230	5.8	Bullnose 5/18 BSP female
J	50.0	137	7.2	4 bar outlet Schraeder
J4	50.0	230	10.5	connector
				Bullnose 5/18 BSP female
				4 bar outlet Schraeder
				connector

Note: (1) Cylinder valves conform to B5341 (non pin-index index – except the 4bar outlet valves which are proprietary)

The cylinders are colour coded as specified in BS 1319 (1976) and ISO 32 (1977).

The colour is a black body with grey and white quartered shoulder.

6.6 Special precautions for disposal

Cylinders should only be used in conjunction with medical oxygen gas pressure regulators.

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, (N.B. See note on "F" size cylinders, above). N.B. Where the 4bar outlet, Schraeder connector valve is fitted, no additional regulator is necessary.
5. Pipelines for medical gases should be installed in accordance with the conditions set out in HTM 2022.
6. 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, 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
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Coleshill
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8 MARKETING AUTHORISATION NUMBER

PL 15929/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/03/1998 / 16/04/2003

10 DATE OF REVISION OF THE TEXT

19/07/2010