SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

5% CARBON DIOXIDE / AIR MEDICAL GAS MIXTURE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

5% Carbon Dioxide / Air Medical Gas Mixture is supplied in high pressure gas cylinders. The Air and the Carbon Dioxide complies with the European Pharmacopoeia Specification (1998) and with their respective Marketing Authorisations.

The mixture specification is as follows:

Carbon Dioxide	5% +/-0.5%
Air	Balance

3. PHARMACEUTICAL FORM

Compressed Medical Gas.

4. Clinical Particulars

4.1 Therapeutic indications

The main use of 5% Carbon Dioxide /Air Gas Mixture is to stimulate respiration after a period of apnoea and in the management of chronic respiratory obstruction after the obstruction has been relieved.

4.2 Posology and method of administration

5% Carbon Dioxide / Air Gas Mixture is administered by inhalation through the lungs usually for a fixed period.
The duration and circumstances of the exposure to 5% Carbon Dioxide / Air Medical Mixture is always at the discretion of the attendant physician who makes the decision in the light of the particular circumstances.

4.3 Contra-indications

There are no contra-indications for the use of 5% Carbon Dioxide / Air Medical Gas
Mixture in any age group.

The duration and circumstances of the exposure to 5% Carbon Dioxide / Air 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 special precautions for use

The administration of 5% Carbon Dioxide / Air 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.

4.5 Interactions with other medicinal products and other forms of interaction

5% Carbon Dioxide / Air Medical Gas Mixture will interact with anaesthetic agents when the concentration is raised and gives rise to cardiac disrhythmias. The threshold for dysrhythmias varies with different drugs.

By altering pH, the use of 5% Carbon Dioxide / Air Medical Gas Mixture influences the uptake and distribution of many drugs, including neuromuscular blocking agents and hypotensive agents.

5% Carbon Dioxide / Air Medical Gas Mixture will interact with adrenergic substances such as adrenaline. They should not be used together.

4.6 Pregnancy and lactation

5% Carbon Dioxide / Air Medical Gas Mixture is not contra-indicated in pregnancy and is unlikely to influence lactation.

4.7 Effects on ability to drive and use machines

The inhalation of 5% Carbon Dioxide / Air 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 5% 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 5% Carbon Dioxide / Air Medical Gas Mixture but its use needs careful supervision.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

5% Carbon Dioxide / Air Medical Gas Mixtures consists of 5% Carbon Dioxide with the balance being Medical Air (or a 21% Oxygen / 79% Nitrogen mixture). 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 -78.50C (at 1 bar)
- density 1.872 kg/m3 (at 150C)

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.

Medical Air

The characteristics of medical air are:

- odourless, colourless gas
- molecular weight 29

- boiling point -1940C (at 1bar)
- density kg/m3 (at 150C)

Atmospheric air contains approximately 21% Oxygen, 78% Nitrogen and 1% Argon with trace contents of other inert gases (Xenon, Neon, Krypton).

The Nitrogen is absolutely inert, but the Oxygen in air is an absolute necessity for life for its cellular respiratory function.

If a normal conscious patient inhales 5% Carbon Dioxide / Air 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 5% Carbon Dioxide / Air 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.

6. Pharmaceutical Particulars

6.1 List of excipients

None.

6.2 Incompatibilities

The constituent gases of 5% Carbon Dioxide / Air Medical Gas Mixture are chemically inactive and will not normally react with other compounds at normal temperatures.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

5% Carbon Dioxide / Air Medical Gas Mixture cylinders should be stored as follows:

- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold away from stocks of material and not subjected to extremes of heat.
- Cylinders should not be stored near stocks of combustible materials or near sources of heat.
- Medical cylinders should be stored separately from industrial and other non-medical cylinders.
- Full and empty cylinders should be stored separately.
- Full cylinders should be used in strict rotation.
- Segregate medical cylinders containing different gases within the store.
- Warning notices prohibiting smoking and naked lights must be posted clearly.
- Emergency services should be advised of the location of the cylinder store.

6.5 Nature and contents of container

5% Carbon Dioxide / Air Medical Gas Mixture Cylinder and Valve Details

5% Carbon Dioxide / Air Medical Gas Mixture is supplied in high pressure cylinders filled to 137 bar(g). Conventional high pressure cylinder valves with side outlets, that conform to BS 341 (5/8" BSP F), are fitted to all 5% Carbon Dioxide / Air Medical Gas Mixture cylinders. These cylinders are designed to be used with a pressure regulator.

A summary of 5% Carbon Dioxide / Air Medical Gas Mixture cylinders, their size and construction and type of valve fitted are detailed below:

Cylinder Size	**Gas Content (litres)**	**Cylinder Construction**	**Cylinder Pressure bar(g)**
AV	1350	Aluminium	137
L	6750	Steel	137

The basic specification for the cylinder valves used in 5% Carbon Dioxide / Air Medical Gas Mixture cylinders is:

Valve Component	**Specification**
Valve Body	High Tensile Brass
Spindle	Steel
Spindle Tip	Nylon 66
Valve Outlet	5/8” BSP (F) Side Outlet
Valve Operation	Handwheel

6.6 Instructions for use and handling

All personnel handling 5% Carbon Dioxide / Air Medical Gas Mixture cylinders should have adequate knowledge of the properties of the gas, precautions to be taken, actions in the event of an emergency and the correct operating procedures for their installations.

Preparation For Use

For 5% Carbon Dioxide / Air Medical Gas Mixture cylinders, prior to use, ensure that:

- an appropriate medical regulator is used with the cylinder suitable for 5% Carbon Dioxide / Air Medical Gas Mixtures.
- the connecting face of the regulator is clean and the sealing washer fitted is in good condition.
- the cylinder valve is opened slowly.
- the cylinder valves and any associated equipment is not lubricated and kept free from oil and grease.

Leaks

Care should be taken to ensure there are no leaks between the regulator connection and the cylinder valve.

The following precautions should be followed:

- Should leaks occur this will usually be evident by a hissing noise.

- Leaks can be found by brushing the suspected area with an approved leak test solution such as 1% Teepol HB7 solution.
- Sealing or jointing compounds must never be used to cure a leak.
- Should a leak occur between the valve outlet and the detachable regulator, depressurise and remove the regulator and fit a new 'O' ring. Reconnect the
  regulator to the valve with moderate force only. If the leak persists, fit a replacement regulator.
- Never use excessive force when connecting equipment to cylinders.

Use Of Cylinders

When cylinders are in use ensure that they are:

- handled with care and not knocked violently or allowed to fall.
- only be moved with the appropriate size and type of trolley or handling device.
- firmly secured to a suitable cylinder support.
- only be used for medicinal purposes.
- not used in the vicinity of persons smoking or near naked lights.

After use the cylinder valves should be closed using moderate force only and the pressure in the regulator released.

When the cylinder is empty ensure that:

- the cylinder valve is closed.
- the valve outlet cap, where fitted, is replaced.
- the empty cylinder is immediately returned to the cylinder store for return to BOC.

7 MARKETING AUTHORISATION HOLDER

BOC Ltd

Forge

43 Church Street West,

Woking,

Surrey,

GU21 6HT,

United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 073515014R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date First Granted:	24 January 1991
Date of Renewal:	02 October 1998

10 DATE OF REVISION OF THE TEXT

04/09/2023