

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

5% Carbon Dioxide / Oxygen Medical Gas Mixture

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

5% Carbon Dioxide / Oxygen Medical Gas Mixture is a medicinal gas mixture of Carbon Dioxide and Oxygen.

The Oxygen and Carbon Dioxide comply with the relevant European Pharmacopoeia Specifications (1998).

The mixture specification is as follows:

Carbon Dioxide	5.0 % +/- 0.5%
Oxygen	Balance
Maximum Impurity Levels	
Carbon Monoxide	5 vpm
Moisture	50 vpm

## 3. PHARMACEUTICAL FORM

Inhalation Gas

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

5% Carbon Dioxide / Oxygen Medical Gas Mixture is used to stimulate respiration after a period of apnoea and in the management of chronic respiratory obstruction after the obstruction has been removed.

### 4.2. Posology and method of administration

5% Carbon Dioxide / Oxygen Medical Gas Mixture is administered by inhalation through the lungs usually for a fixed period.

### **4.3. Contraindications**

There are no contraindications for the use of 5% Carbon Dioxide / Oxygen Medical Gas Mixture in any age group.

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

Administration of 5% Carbon Dioxide /Oxygen 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.

Where the patient has been exposed to agents which are toxic to the lungs, such as Paraquat, the use of gases containing more than 21% oxygen should be avoided.

5% Carbon Dioxide /Oxygen Medical Gas Mixture is non flammable but strongly supports combustion and should not be used near sources of ignition.

Smoking should be prohibited when using 5% Carbon Dioxide /Oxygen Medical Gas Mixture.

Under no circumstances should oils or grease be used to lubricate any part of the 5% Carbon Dioxide /Oxygen Medical Gas Mixture 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 5% Carbon Dioxide /Oxygen Medical Gas Mixture cylinders or equipment.

### **4.5 Interaction with other medicinal products and other forms of interaction**

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

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

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

The use of higher levels of oxygen can increase the risk of pulmonary toxicity in patients who have been administered Bleomycin, Amiodarone and Nitrofurantoin or similar antibiotics. In these cases Medical Oxygen/Carbon dioxide mixtures should be administered with caution and at levels kept as low as possible.

#### **4.6. Pregnancy and lactation**

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

#### **4.7. Effects on ability to drive and use machinery**

The inhalation of 5% Carbon Dioxide / Oxygen 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](http://www.mhra.gov.uk/yellowcard)

#### **4.9. Overdose**

No overdose effects are seen with 5% Carbon Dioxide / Oxygen Medical Gas Mixture

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacological properties**

The characteristics of Carbon Dioxide are:

- odourless, colourless gas
- Molecular weight 44
- Boiling point -78.50C (at 1 bar)
- Density 1.872 kg/m<sup>3</sup> (at 15°C)

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.

The characteristics of Oxygen are:

- odourless, colourless gas
- Molecular weight 32
- Boiling point -183.1°C (at 1 bar (g))
- Density 1.355 kg/m<sup>3</sup> (at 15°C)

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

If a normal conscious patient inhales 5% Carbon Dioxide / Oxygen 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 / Oxygen 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 stated

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

None.

### **6.2. Incompatibilities**

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

However the Compressed Medical Oxygen component of 5% Carbon Dioxide / Oxygen Medical Gas Mixture strongly supports combustion and will cause substances to burn, including some materials that will not normally burn in air. It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion in the presence of Compressed Medical Oxygen in relatively high concentrations.

### **6.3. Shelf life**

36 months

### **6.4. Special precautions for storage**

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

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

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

Cylinder Size	Gas Content (litres)	Cylinder Construction	Valve Outlet	Valve Construction
F	1360	Steel	BS 341 No.3 Top outlet MPR Valve	Brass
AV	1500	Aluminium	BS 341 No.4 Side outlet	Brass
G	3400	Steel	BS 341 No.3 Top Outlet MPR Valve	Brass
J	6800	Steel	BS 341 No.3 Top Outlet MPR Valve	Brass
AK	6000	Aluminium	BS 341 No.3 Side Outlet	Brass

The cylinder valves are constructed from high tensile brass with a steel spindle fitted with a Nylon 66 insert.

## 6.6 Instructions for use and handling ( and disposal)

All personnel handling 5% Carbon Dioxide / Oxygen 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

Prior to use ensure that:

- The connecting face of the regulator is clean and the sealing ring 'O' ring 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 cylinder with moderate force only.
- Never use excessive force when connecting equipment to cylinders.

### **Use of Cylinders**

For 5% Carbon Dioxide / Oxygen Medical Gas Mixture 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 medical purposes.
- Not used in the vicinity of persons smoking or near naked lights.

After use the 5% Carbon Dioxide / Oxygen Medical Gas Mixture cylinders valves should be closed using moderate force only.

When the cylinder is empty ensure that:

- The cylinder valve is closed.
- 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 00735/5010R

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

02/11/2005

**10 DATE OF REVISION OF THE TEXT**

20/10/2022