Package Insert

Sabah Oxygen MEDICAL CARBON DIOXIDE 100%v/v

1. Product Name

Sabah Oxygen MEDICAL CARBON DIOXIDE 100%v/v

2. Name and Strength of Active Substance(s)

Medical Carbon Dioxide 100%v/v, Liquefied Medicinal Gas, Compressed.

There are no excipients in this product.

3. Product Description

Medical Carbon Dioxide is colourless and odorless. The product is stored in French grey coloured cylinder. It is stored in the form of liquefied gas.

4. Pharmacodynamics

Pharmacotherapeutic Group- Medical Gas

ATC Code: V03AN02

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.

5. Pharmacokinetics

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.

6. Indications

Medical Carbon Dioxide is used for:

- 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.

7. Recommended Dosage

Dosage

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.

8. Route of Administration

Inhalation.

9. Contraindications

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

10. Warnings and Precautions

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 incontact 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.

11. Interaction with other Medicaments

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.

12. Pregnancy and Lactation

The use of carbon dioxide is not recommended in pregnancy but is unlikely to influence lactation.

13. Side 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.

14. Symptoms and Treatment of 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 s similar to anaesthetics. All anaesthetic agents reduce the responses to carbon dioxide. The effects are reversed when the breathing of carbon dioxide ceases.

15. Effects on Ability to Drive and Use Machines

Inhalation of carbon dioxide is not compatible with driving or use of machinery.

16.Instruction of Use

Precautious and Preparation for Use

- Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.

- Cylinder valves and any associated equipment must never be lubricated and must be kept free from oil and grease.

- Medical gases must only be used for medicinal purposes.

- Remove the cylinder seal cap from valve before use.

- Cylinder valves should be opened momentarily prior to use to blow any foreign matter out of the outlet.

- Only the appropriate regulator should be used for the particular gas concerned.

- Never use excessive force when connecting equipment to cylinders.

- Cylinder valves must be opened slowly.

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

- 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 supplier for repair.

- Sealing or jointing compounds must never be used to cure a leak.

Use of Cylinders

- Cylinders containing liquefiable gas must always be used vertically with the valve uppermost.

- Cylinders should only be moved with the appropriate size and type of trolley.

- Cylinders should be handled with care and not knocked violently or allowed to fall.

- When in use cylinders should be firmly secured to a suitable cylinder support.

- 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.

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

Disposal

- Used cylinders should be returned to supplier immediately.

17.Storage Condition

Medical Carbon Dioxide cylinders should be:

- Prohibiting smoking and naked flame in the storage area.

- Cylinders should be stored indoor, kept dry and clean.

- Kept away from any flammable materials.

- Store in a well ventilated place.

- Store in upright position and secure it.

- Full and used cylinders should be stored separately. Full cylinders should be used in strict rotation.

- Medical cylinders containing different gases should be segregated and identified within the store.

- Cylinders must not be repainted, have any markings obscured or labels removed.

- Store at temperature below 50 °C.

18. Shelf Life

3 years

19. Contents of Container

Medical Carbon Dioxide is supplied as Liquefied gas stored in steel cylinders equipped with BullNose valves.

Cylinder Size (L water capacity)	Content (Kg)	Cylinder Material	Valve
41	25	Steel	Bullnose
47	30	Steel	Bullnose

20. Name and Address of Manufacturer/product register holder

SABAH OXGEN SDN. BHD.

Lot No. 30, Jalan 2A KKIP Timur, Industrial Zone 12 (IZ12), Kota Kinabalu Industrial Park (KKIP), 88460 KOTA KINABALU SABAH, MALAYSIA

21. Product Registration Number

MAL24126040X

22. Date of Revision of the Text

5/8/2024