**a) Brand or Product Name**
Mega Mount Medicinal Carbon Dioxide 100% v/v.

**b) Name and Strength of Active Substance(s)**
Medicinal Carbon Dioxide 100%v/v, liquefied medicinal gas, compressed.
There are no excipients.

**c) Product Description**
Medicinal Carbon dioxide gas is colourless and odorless. The product is stored in French grey coloured cylinder. It is stored in the form of liquefied gas.

**d) 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.

**e) 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 5 kPa (40mmHg) 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 mmHg) per minute.

**f) Indication**
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.

**g) Recommended 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.

**h) Route of Administration**
Inhalation.

**i) Contraindications**
Carbon dioxide should not be used in acidosis, in respiratory obstruction and during resuscitation.

**j) 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 in contact 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.

**k) Interactions 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.

**l) Pregnancy and Lactation**

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

**m) 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.

**n) Symptoms and Treatment of Overdose**

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 - 2minutes at 20%. When the concentration is raised to 30%, consciousness is lost rapidly, the blood pressure may rise to 27 kPa (200 mmHg) 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.

**o) Effects on Ability to Drive and Use Machine**

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

**p) Instruction for Use**

1. To prepare the cylinder for use, before placing near the patient:
   - Remove the tamper evident seal and the valve outlet protection cap.
   - Ensure the cap is retained so that it can be refitted after use
   - Ensure the batch label fitted to the cylinder is not removed or discarded
   - Ensure that an appropriate compressed medical regulator or manifold tailpipe is selected for connection to the cylinder
   - Ensure the connecting face on the regulator is clean and the sealing washer fitted is in good condition
   - Connect the regulator or tailpipe, using moderate force only and where appropriate connect the tubing to the regulator/flowmeter outlet. Only the appropriate regulator should be used for the particular gas concerned
   - Open the cylinder valve slowly and check for any leaks.
2. Medical Cylinders should be set up and tested before placing near the patient. Do not place the cylinder on the patient's bed unless there is no suitable alternative for retaining the cylinder.

**q) Storage Conditions**

1. Medical carbon dioxide cylinders should be:
   - Stored under cover, preferably inside, kept dry and clean, and not subjected to extremes of heat or cold and away from stocks of combustible material.
   - Store at temperature below 50°C.
   - Stored separately from industrial and other non-medical cylinders.
   - Stored to maintain separation between full and empty cylinders.
   - Used in strict rotation so that cylinders with the earliest filling date are used first.

- Stored separately from other medical cylinders within the store.

2. Warning notices prohibiting smoking and naked lights must be posted clearly in the cylinder storage area and the Emergency Services should be advised of the location of the cylinder store.
3. Care is needed when handling and using medical carbon dioxide cylinders.

**r) Dosage forms and packaging available**

Dosage: Liquefied medicinal gases, compressed

Packaging:

| Cylinder Material | Cylinder Size (L) | Valve | Pressure (bar) | Content (kg) |
|---|---|---|---|---|
| Alumunium or Carbon Steel | 1.7 | Bullnose BS 341 No. 8, or pin index ISO 407 or CGA940 | 150 | 1 |
| | 2.3 | | 150 | 1.3 |
| | 2.5 | | 150 | 1.6 |
| | 3.2 | | 150 | 2 |
| | 5.0 | | 150 | 3 |
| | 10 | | 150 | 6 |
| | 12.0 | | 150 | 7 |
| | 15.5 | | 150 | 9 |
| | 20.0 | | 150 | 10 |
| | 41 | | 150 | 25 |
| | 47 | | 150 | 28 |
| | 50 | | 150 | 30 |

**s) Name and address of manufacturer/ product registration holder**

Mega Mount Sdn. Bhd.
PLO 192, Jalan Siber 8, Kawasan Perindustrian Senai IV,
81400 Senai, Johor, Malaysia

**t) Product Registration number:**

MALxxxxxxxxX

**u) Date of revision of PI**

Rev00 08-Sep-2025