a) Brand or Product Name

Mega Mount Medical Air (19.5-23.5%v/v Oxygen Balance Nitrogen, Synthetic).

b) Name and Strength of Active Substance(s)

Oxygen, 19.5-23.5%v/v.

c) Product Description

This product is synthetic medicinal air where it is produced by mixing 19.5% to 23.5% v/v pure oxygen gas with pure nitrogen gas.
Synthetic gas mixtures are carefully controlled to meet specific standards and application requirements.
Oxygen gas (O2) is a diatomic molecule, meaning it consists of two oxygen atoms bonded together. In its gaseous state, oxygen is colorless, odorless, and tasteless. It is also highly reactive and supports combustion.
The standard colour of cylinder that contains synthetic medicinal air has a grey coated body with white and grey shoulder stripes.
It is compressed gas up to 200 bars at 27°Celsius.

d) **Pharmacodynamics**

Pharmacotherapeutic group: Other therapeutic products-medicinal gases
ATC code: V03AN05
The characteristics of medical air are:
• Odourless, colourless gas
• Molecular weight 29
• Boiling point -194°C (at 1 bar (g))
• Density 1.225 kg/m^3 (at 15°C)
Oxygen is vital to life and must be continuously supplied to all tissues in order to maintain the cells' energy production. Ambient air contains approximately 21% oxygen and 79% nitrogen. Synthetic air contains 21% oxygen, and 79% nitrogen and is mainly used because of its oxygen content.
The final target for the oxygen is the mitochondria in the individual cells, where oxygen is consumed in an enzymatic chain reaction, forming energy. Oxygen (in the form of reactive oxygen species) is also essential to several immunological defence mechanisms.

e) Pharmacokinetics

Nitrogen gas is in equilibration in the total lung volume and has no pharmacological effects in the body.
Nitrogen may be considered as inert.
Synthetic air contains approximately 21% oxygen, which is almost identical to the concentration of oxygen in ambient air. It is administered via the airways to the lung. In the pulmonary alveoli, gas exchange, down a partial pressure gradient, takes place from the inspired air/gas mixture to the capillary blood.
The oxygen is transported by the systemic circulation mainly bound to haemoglobin to the capillary beds in the different tissues in the body. Only a very small portion is free, dissolved in plasma. During passage through the tissues, a partial pressure-dependent transport of the oxygen to the individual cells takes place. Oxygen that is absorbed in the body is excreted almost entirely as carbon dioxide formed in the intermediary metabolism. Nitrogen is not absorbed, and is exhaled without having undergone any conversion/ metabolism.

f) Indication

Medical Air is used:
• as a replacement for atmospheric air when the atmosphere is contaminated by noxious fumes, vapours or gases
• in anaesthesia as a carrier gas for volatile anaesthetic agents
• in ventilators and incubators to provide uncontaminated and controlled air flows
• as a power source for pneumatic equipment

g) Recommended Dosage

For breathing purposes Medical Air is administered by various means, commonly by self-contained or compressed air line breathing apparatus.
In anaesthesia, Medical Air is administered via a cylinder and valve assembly through a face mask or endotracheal tube.

h) Route of Administration

Inhalation.

i) Contraindications
There are no absolute contraindications.

j) Warnings and Precautions
Medical Air should never be administered to a patient if, when it is mixed with other gases, the Oxygen content is less than 21%.
Medical Air is non-flammable but strongly supports combustion and should not be used near sources of ignition.

k) Interactions with Other Medicaments
There are no reports of interaction with Medical Air.

l) Pregnancy and Lactation
Pregnancy - Medical Air can be used during pregnancy.
Breastfeeding- Medical Air can be used during lactation.
Fertility - Medical Air has no known negative effects on fertility.

m) Side Effects
No other undesirable side effects.

n) Symptoms and Treatment of Overdose
Not applicable.

o) Effects on Ability to Drive and Use Machine
The use of Medical Air does not affect the ability to drive or use 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.
- Synthetic Medical Air is non-flammable but strongly supports combustion and should not be used near sources of ignition.

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.
3. Smoking should be prohibited when using medical gases. Under no circumstances should oils or grease be used to lubricate any part of the gas cylinder or the associated equipment used to deliver the gas to the patient.
4. Where moisturising creams are required for use with a facemask or in nasal passages, oil-based creams should not be used.
5. Check that hands are clean and free from any oils or grease.
6. Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling medical gas cylinders or equipment.

q) Storage Conditions
1. Medical Air 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
- 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 expiry date are used first

- stored separately from other medical cylinders within the store
- cylinders should be stored vertically

2. Recommended storage temperature for medical air is below 50 °Celsius.
3. 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.
4. Care is needed when handling and using medical air cylinders.

r) Dosage forms and packaging available

Dosage: Medicinal gases, compressed

Packaging:

Cylinder Material	Cylinder Size (L)	Valve	Pressure (bar)	Content (m^3)
Carbon Steel	3.4	Bullnose (BS 341) or Pin Index (ISO 407 or CGA950)	150	0.5
	5.0		150	0.7
	10		150	1.4
	30		150	3.4
	45		150	6.4
	46.7		150	7.0
	47		150	7.2
	50		200	9.6

s) Name and address of manufacturer/ product registration holder

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t) Date of revision of PI

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