



PACKAGE INSERT

GPT MEDICINAL AIR 100% V/V

BRAND OR PRODUCT NAME

GPT Medicinal Air 100% v/v.

NAME AND STRENGTH OF ACTIVE SUBSTANCE(S)

Medicinal Air 100%v/v, Medicinal Gas, Compressed.

There are no excipients.

PRODUCT DESCRIPTION

The medicinal air is non-flammable, colourless, and odourless gas.

The physical appearance of container is black & white color cylinder shoulder and French grey color cylinder body.

The cylinders are filled with medicinal gas at a pressure of 150 bar.

PHARMACODYNAMICS

Pharmacotherapeutic group: Medical gases; ATC code: V03AN05.

Medicinal air contains 21 % oxygen and the remaining part is nitrogen gas, which must be considered inert. Medicinal air is mainly used on account of its oxygen content, which corresponds completely to room air.

Oxygen is vital for human life, and must be supplied continually to all tissues in order to maintain the cells' energy production. Its target is the mitochondria in the individual cells, where the oxygen takes part in an enzymatic chain reaction, which creates energy, aerobic metabolism.

Nitrogen may be considered as inert.

PHARMACOKINETICS

Medicinal air consists of 21 % oxygen, which corresponds completely to the concentration in normal room air/surrounding air. It is administered by inhalation and it is transported via the airways to the lungs. In the pulmonary alveoli, as a result of the difference in partial pressure, a gas exchange takes place from the inspired air/gas mixture to the capillary blood. The oxygen is transported further with the systemic circulation, for the most part bound to haemoglobin and only a very small part is freely dissolved in plasma, to the capillary beds in the different tissues of the body. The oxygen is transported with the aid of the pressure gradient out to the various cells.

Oxygen that is absorbed in the body is excreted almost completely as carbon dioxide formed in the intermediate metabolism.

Nitrogen is not absorbed. It follows the expiratory air without having undergone any conversion/metabolism.



INDICATIONS

Medicinal air is used by inhalation and indicated as a replacement for ordinary ambient/atmospheric air whenever it is needed e.g.:

- During ventilatory therapy and/or in anaesthesia, as part of the fresh gas flow, e.g. combined with oxygen, in order to achieve a desired inspired oxygen fraction
- As a driving/carrier gas for nebulisation
- As source of clean air for immune-suppressed patients (e.g. post organ/cell transplants or severe burns)
- To power air driven medical equipment

Medicinal air is indicated in all age groups.

RECOMMENDED DOSAGE

The dosage of administered medicinal air should be titrated against the respiratory status of the individual patient. Respiratory rate, arterial oxygenation and carbon dioxide tension, should be reviewed at periodic (clinically determined) intervals.

The purpose of the use of medicinal air is to ensure a safe administration of gas with oxygen content identical to ambient air and not contaminated by fumes or other potential irritant substances.

Medicinal air is mainly indicated as a replacement for ambient air. Whenever needed, medicinal air should be mixed with medicinal oxygen in order to create a gas mixture with the desired oxygen fraction/concentration to ascertain adequate oxygenation (measured with PaO₂, or SaO₂, or SpO₂), according to the following calculation:

$$FiO_2 = (X \text{ I air} \times 0.21) + (Y \text{ I O}_2 \times 100) / Z \text{ I gas mixture}$$

FiO₂: fraction of inspired oxygen

X: flow of administered medicinal air

Y: flow of administered medicinal oxygen

Z: total flow of administered gas mixture

Paediatric population

The safety and efficacy of oxygen in children of all ages is well established. The dosing instructions for the paediatric population are the same as for adults.

Method of administration

Medicinal air is administered by special devices as part of the inspiratory gas-mix by inhalation. On exhalation, the exhaled gas leaves the patient together with any oxygen and mixes with the surrounding ambient air.

Spontaneous breathing

There are a large number of devices intended for the administration of medicinal air combined with prescribed amounts of oxygen in spontaneously breathing patients.

When medicinal air is administered combined with oxygen, the gas can be administered by e.g. nasal cannula, facial mask, facial tent, oxygen hood or tracheostomy.

Assisted and controlled ventilation

If the patient cannot breathe independently, medicinal air can be used in ventilatory therapy for artificial breathing support. When oxygen is administered by assisted or controlled ventilation, an oxygen air



mixture is commonly used in order to achieve a desired oxygen fraction. The gas can be administered by mask, tracheal tube or tracheostomy.

Fresh gas flow during general anaesthesia

Special devices are commonly used with either re-breathing reservoirs or recycling devices, which allow a portion of the expired gas to be inhaled again.

ROUTE OF ADMINISTRATION

Inhalation.

CONTRAINDICATIONS

None known.

WARNINGS AND PRECAUTIONS

Medicinal air should never be given unless it contains 20.4 - 21.4% oxygen. If medicinal air is mixed with other inhaled agents, the oxygen fraction in the inhaled mixture should always be kept to at least 0.21 (21%). In practice, this means that if medicinal air is a component of a gas mixture, oxygen should be one of the other components. The oxygen fraction should be carefully considered whenever higher inspired oxygen fractions are needed.

There is a risk for expansion of gas filled spaces, which eventually can lead to volu/baro trauma if there is no possibility to vent. The administration of continuous flow of any gas filled space will cause an increase in pressure. In case the gas influx is higher than the uptake and the gas passage out of the space, the pressure may increase to such an extent that the organ ruptures. A pressure reduction valve in the delivery equipment prevents insufflating above its lung capacity and thereby the risk of volutrauma.

Paediatric population

There are no additional warnings or precautions than those in the adult population.

INTERACTION WITH OTHER MEDICAMENTS

None known.

PREGNANCY AND LACTATION

Pregnancy

Medicinal air can be used during pregnancy.

Breastfeeding

Medicinal air can be used during lactation.

SIDE EFFECTS

None known.

SYMPTOMS AND TREATMENT OF OVERDOSE

Not applicable.



EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Medicinal air has no influence on the ability to drive and use machines.

INSTRUCTION FOR USE

General precautions

- Medicinal gases must only be used for medicinal purposes.
- Do not smoke or use a naked flame in areas where medicinal gases are administered.
- Never use oil or grease, even if the cylinder valve is stiff or if the regulator is difficult to connect.
- Handle valves and equipment to match with clean and grease-free (hand cream, etc.) hands.
- Never place a mask or nasal prongs directly on textiles while treatment is being carried out since fabrics that become saturated with oxygen can be highly flammable and cause a risk of fire. If this should occur, thoroughly shake and air the textiles.
- In case of cleaning of cylinders or attached equipment, do not use combustible products and especially not oil-based material. In case of doubt, verify compatibility.
- Prior to any use, ensure sufficient quantity of product remains to allow completion of the planned administration.
- Use only standard equipment that is intended for medicinal air.
- Do not use medicinal air if the cylinder is damaged or has the tamper evident plastic seal removed.

Preparation for use

1. Ensure the correct regulator is used for the intended purpose.
2. Ensure connection, fitting and line are leak tight and suitable for use.
3. Ensure that flammable and oxidizing gases are not used near ignition sources.
4. Cylinder should be used and stored in clean, well-ventilated, and dry conditions, which are not exposed to heat or cold.
5. Close the cylinder valve when not in use.

STORAGE CONDITIONS

- Cylinders should be stored in a well-ventilated area reserved for the storage of medicinal gases. Avoid exposure to direct sunlight.
- Cylinders should be stored at temperatures below +50°C.

SHELF LIFE

3 years.

DOSAGE FORM AND PACKAGING AVAILABLE

Dosage form

Medicinal gas, compressed.

Packaging

The cylinders are made of carbon steel, equipped Pin-Index Valve or Bull nose Valve.

The cylinder body is painted French grey color and the cylinder shoulder is painted black & white.



Cylinder size (L water capacity)	Valve type	Cylinder material	Settled Pressure at 27°C (1 bar)	Content (m ³ Air at 27°C, 1 bar)
3.4 L	Pin Index MS ISO407:2006 or Bull Nose BS 341 No.3 (Top Outlet)	Steel	150	0.5
5.0 L	Pin Index MS ISO407:2006 or Bull Nose BS 341 No.3 (Top Outlet)	Steel	150	0.7
10.0 L	Pin Index MS ISO407:2006 or Bull Nose BS 341 No.3 (Top Outlet)	Steel	150	1.4
40.0 L	Pin Index MS ISO407:2006 or Bull Nose BS 341 No.3 (Top Outlet)	Steel	150	6.4
47.0 L	Pin Index MS ISO407:2006 or Bull Nose BS 341 No.3 (Top Outlet)	Steel	150	7.0

Not all pack sizes may be marketed.

NAME AND ADDRESS OF PRODUCT REGISTRATION HOLDER / MANUFACTURERProduct Registration Holder

Gas Pantai Timur Sdn Bhd (58757-T)
Lot 300733 & 300734, Kawasan Perindustrian Gopeng
31600 Gopeng, Perak Darul Ridzuan, Malaysia

Manufacturer

Gas Pantai Timur Sdn Bhd (58757-T)
Lot 300733 & 300734, Kawasan Perindustrian Gopeng
31600 Gopeng, Perak Darul Ridzuan, Malaysia

DATE OF REVISION

01-Nov-2024