PACKAGE INSERT

LINDE MEDICINAL AIR 100% v/v

1. BRAND OR PRODUCT NAME

Linde Medicinal Air 100%v/v

2. NAME AND STRENGTH OF ACTIVE SUBSTANCE(S)

Medicinal Air 100%, Medicinal Gas, Compressed

There are no excipients.

3. PRODUCT DESCRIPTION

The drug product air medicinal is packaged in gas cylinders as compressed air. It 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 gaseous air with pressure of 144 and 150bar respectively.

4. PHARMACODYNAMICS

Pharmacotherapeutic group: Other therapeutic products - medicinal gases, ATC code: V03AN05.

Medicinal air contains approximately 21% oxygen, and 79% nitrogen.

Oxygen is vital to life and must be continuously supplied to all tissues in order to maintain the cells' energy production. Medicinal air is mainly used because of its oxygen content, which is identical to that of ambient air.

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 a number of immunological defence mechanisms.

Nitrogen gas is in equilibration in the total lung volume and in the body and has no pharmacological effects. Nitrogen may be considered as inert.

5. PHARMACOKINETICS

Medicinal air contains approximately 21% oxygen, which is identical to the concentration of oxygen in normal room 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.

6. 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.

7. 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:

$$FiO_2 = (X \text{ l air} \times 0.21) + (Y \text{ l } O_2 \times 100) / Z \text{ l gas mixture}$$

FiO_2: 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.

8. METHOD OF ADMINISTRATION

Precautions to be taken before handling or administering the medicinal product, see special precautions for disposal and other handling.

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.

9. ROUTE OF ADMINISTRATION

Inhalation

10. CONTRAINDICATIONS

There are no absolute contraindications.

11. WARNINGS AND PRECAUTIONS

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.

12. INTERACTION WITH OTHER MEDICAMENTS

There are no described interactions with medicinal air.

Paediatric population

There are no described interactions with medicinal air.

13. PREGNANCY AND LACTATION

Pregnancy

Medicinal air can be used during pregnancy.

Breastfeeding

Medicinal air can be used during lactation.

Fertility

Medicinal air has no known negative effects on fertility.

14. SIDE EFFECTS

No undesirable effects are known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 *NPRA's ADR (Adverse Drug Reactions) reporting website: npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].*

15. SYMPTOMS AND TREATMENT OF OVERDOSE

Not applicable.

Paediatric population

The risk for overdose in the paediatric populations is the same as in the adult population.

16. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

17. PRECLINICAL SAFETY DATA

Not applicable.

18. INSTRUCTION FOR USE

General precautions

- Do not smoke or use a naked flame in areas where medicinal gases are administered.
- Medicinal gases must only be used for medicinal purposes.
- Never use grease, oil or similar substances, even if the cylinder valve sticks or if the regulator is difficult to connect.
- Handle valves and devices belonging to them with clean and grease-free hands (i.e. no use of hand cream etc.).
- 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.
- Only use standard devices designed for administration of medicinal product.

- When delivered from the manufacturer, the cylinders should have an intact tamper evident seal.

Preparation for use

- Remove the plastic cover from the valve before use.

The instructions below are applicable for cylinders where a separate pressure regulator shall be connected before use:

- Use only regulators designed for product.
- Check that the connection on the coupling or regulator is clean and that the connections are in good condition.
- Never use pliers to force regulators that are designed to be connected manually, as this can damage the connection.
- Check that the regulator is properly attached before opening the valve.
- Open the cylinder valve gently, at least half a turn.
- Check for leakage according to instructions that accompany the regulator.
- In the event of leakage, close the valve and disconnect the regulator. Mark the defective cylinder, keep it separate and return it to your supplier.

Use of cylinders

- Close the cylinder in the event of fire or when not in use.
- Ensure cylinders are secured to a suitable cylinder support in vertical position when in use, to prevent them from falling.
- For cylinders equipped with integrated valves, the user should be prepared to change the cylinder when the pressure gauge is in the yellow zone and change it when it enters the red zone.
- For cylinders that are not equipped with residual pressure valves, the cylinder valve should be closed when a small amount of gas remains in the cylinder (approx. 2 bars). It is important to leave a slight residual pressure in the cylinder in order to protect it from contamination.
- After use, the cylinder valve should be closed with normal force and the regulator or connection depressurised.

Transportation of cylinder

- When being transported, the cylinders must be secured to prevent them from falling.
- Larger cylinders should be transported with appropriate type of trolley. Particular attention should be paid to ensuring connected devices are not accidentally loosened.

Special precautions for disposal and other handling

The cylinder package must not be disposed but returned to the supplier.

19. STORAGE CONDITIONS

- Do not smoke or use a naked flame in areas where medicinal gases are stored.
- Cylinders should be stored in a well-ventilated area reserved for the storage of medicinal gases.
- Cylinders should be stored under cover, kept dry and clean, kept free from oil and grease, free from flammable material.
- Cylinders should be stored at temperatures below +50°C

- Precautions should be taken to prevent blows or falls.
- Cylinders containing different types of gases should be must be stored separately.
- Full and empty cylinders should be stored separately.
- Cylinders should be stored and transported with valves closed.
- After delivery from the manufacturer a cylinder must have an undamaged plastic valve cover

20. SHELF LIFE

3 years.

21. DOSAGE FORM AND PACKAGING AVAILABLE

Dosage form

Medicinal gas, compressed.

Packaging

The cylinders are made of Aluminium or steel equipped Pin-Index or BullNose valves.

The cylinder body is painted light Black & White and the cylinder shoulder is painted French Grey

Cylinder size (L water capacity)	Valve type	Cylinder material	Filling pressure at 27°C (1 bar)	Content (m^3 Air at 27°C, 1 bar)
4L	Pin-Index	Aluminium	144	0.5
5L	Pin-Index	Aluminium	144	0.7
10L	Pin-Index / BullNose	Aluminium	144	1.4
45L	BullNose	Steel	150	7.1
47L	BullNose	Steel	150	6.4
50L	BullNose	Steel	150	8.0

Not all pack sizes may be marketed.

22. NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER

Manufacturer:

Linde Gas Products Malaysia Sdn Bhd (453560-K)
P.O.BOX 10633, GPO KUALA LUMPUR, 50670 WPKL.
No. 1, Jalan Graphite 3, Kawasan Perindustrian Bandar Mahkota Banting,
42700 Banting, Kuala Langat, Selangor Darul Ehsan

Product Registration Holder:

Linde Malaysia Sdn. Bhd (100783-W)
Level 13, The Pinnacle Persiaran Lagoon, Bandar Sunway,
47500 Petaling Jaya, Selangor Darul Ehsan
03-56248888
03-56113512
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23. PRODUCT REGISTRATION NUMBER(S)

MAL23126002X

24. DATE OF REVISION OF THE TEXT

24 Sep 2024

— END —

Version History

Version	Date	Changes
1	16 Nov 2023	Original issue. Adapted from 29026, version 10, Effective date: 2022 Dec 05. Updated as per the NPRA PI requirement.
2	24 Sep 2024	Update product registration number