

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Medicinal Air Synthetic 21.75% v/v medicinal gas compressed.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxygen 21.75% v/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicinal gas, compressed

Medicinal Air Synthetic is a colourless, odourless and tasteless gas.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of hypoxia where treatment with atmospheric air is indicated.

4.2 Posology and method of administration

Posology

The flow rate and duration of administration should be determined based on the cause of the hypoxia.

Method of administration

A physician, experienced in intensive care or pneumology, should see to the administration of medicinal air as inlet gas for respirators used in respiratory support.

For long-term administration, humidification is advised.

Medicinal air is administered via inhaled air, preferably by means of dedicated equipment (for example, a nasal cannula, facial mask, facial tent, an oxygen tent over a crib, or flow to tracheotomy). Such devices must be used according to the instructions of the manufacturer. Through this equipment, medicinal air is administered along with inhaled air. Upon exhaling, the exhaled gas leaves the patient together with any surplus air and mixes with the ambient air (“non-rebreathing” system).

If the patient is not able to breathe independently, artificial breathing support can be provided.

General

Connections for tubes, valves, etc., must be clean and dry. If needed, clean them according to the instructions of the supplier. Do not use solvents.

Do not use oil or grease on the cylinder valve or the related equipment.

4.3 Contraindications

There are no absolute contraindications.

4.4 Special warnings and precautions for use

Medicinal air may only be administered to patients under atmospheric pressure or at pressure levels that are slightly positive, when ventilators are used.

Administration of medicinal air under pressure could cause decompression sickness (as a result of the effects of nitrogen) and oxygen toxicity.

If medicinal air is mixed with other inhalation gases, the oxygen fraction in the inhaled mixture (Fraction of inspired oxygen – FiO₂) must be kept at least at 21% v/v. Practically speaking, this means that if it is a component of a gaseous mixture, oxygen must be one of the other components.

At extremely high flow rates, such as in an incubator, medicinal air may feel cold.

Medicinal air should not be used where higher than atmospheric concentrations of oxygen (>21%) would be indicated.

Paediatric population

Children differ from adults, in more ways than just in size: they have, for example, a different breathing pattern, tidal volume and geometry of the airways. Caution is needed in relation to the use in children.

Before and during intake of the medicine, strict compliance with the safety precautions specified below is essential.

SAFETY (see also sec. 6.6)

It must be said that air is not flammable per se but oxygen supports combustion; hence, when there are combustible substances, such as fats (oils, lubricants) and organic substances (fabrics, wood, paper, plastic materials, etc.), oxygen can activate combustion when exposed to a trigger (sparks, naked flame, source of ignition), or as a result of adiabatic compression, which can occur in pressure reducing devices (reducers) during sudden reduction in gas pressure.

- Medicinal gas cylinders must be kept far from sources of heat due to the combustibility of oxygen; hence, due precautions must be taken in this regard.
- Oxygen can cause a sudden fire of incandescent materials or of embers; hence, it is not allowed to either smoke or keep naked flames that are not screened near the cylinders and supplying systems.
- Do not smoke in the room where medicinal air is being administered.
- Do not place the cylinders near heat sources.

- Do not use any electrical equipment that can issue sparks near the patients who receive medicinal air.
- It is absolutely forbidden to intervene in any way on cylinder connections, on supplying devices and on the related accessories or components.
- All contact with oil, fats or other hydrocarbons must be avoided (**OIL AND FATS CAN SPONTANEOUSLY CATCH FIRE IN CONTACT WITH OXYGEN**).
- It is absolutely forbidden to handle devices or components with hands or clothes or face soiled with grease, oil, creams and miscellaneous ointments. Do not use either oily creams or lipsticks.
- Cylinders cannot be used, if there is any evident damage or a suspicion that they have been damaged or exposed to extreme temperatures.
- Only suitable devices that are compatible for the specific model of the cylinder can be used.
- Neither pliers nor other utensils can be used to either open or close the cylinder's valve in order to prevent the risk of damage.
- In case of leakage, the cylinder's valve must be instantly closed, if this can be done safely. If the valve cannot be closed, the cylinder must be moved to a safer outdoor location to allow the air to be freely released.
- The valves of empty cylinders must be kept closed.
- Administering gas under pressure is not allowed.

4.5 Interaction with other medicinal products and other forms of interaction

There have been no reports of interactions with medicinal air.

The only interactions known are related with 100% v/v oxygen Paediatric population

No interactions have been reported in children or adolescents. No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Medicinal air may be used during pregnancy and breast-feeding.

Insufficient animal studies of *medicinal compressed air* have been conducted in relation to the effects on fertility and/or postnatal development. There are no known potential risks for humans.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

No undesirable effects are known also from post-marketing surveillance.

Paediatric population

No undesirable effects have been reported in children or adolescents.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 the national reporting system:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

No cases of overdose have been reported under normal pressure (1 bar).

Paediatric population

No cases of overdose have been reported in children or adolescents.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Medical gases, ATC code: V03AN05.

Pharmacodynamic effects

The active ingredient, oxygen, is an essential element for sustaining life. The pharmacodynamic elements of medicinal air are linked to the physiological respiration.

Air contains approximately 21% oxygen, equivalent to (at normal atmospheric pressure) a partial pressure of 159 mmHg. The purpose of physiological respiration is to maintain an oxygen supply sufficient enough to comply with the metabolic demands of tissues.

5.2 Pharmacokinetic properties

Inhaled oxygen is absorbed by pressure-dependent gas exchange between alveolar gas and the capillary blood passing the alveoli. Oxygen (mainly bound to haemoglobin) is transported to all body tissues via the systemic circulation. Only a very small fraction of it is free oxygen (dissolved in plasma). Oxygen is an essential component in the intermediary metabolism of the cell for the formation of energy-aerobic ATP production in the mitochondria. The oxygen absorbed by the body is almost completely eliminated as carbon dioxide, which is formed during this intermediate mechanism.

5.3 Preclinical safety data

Since this product is virtually equivalent to ambient air, no specific risks are to be expected for human health.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nitrogen 78.25% v/v.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

- The gas cylinders should be stored between -20°C and +65°C.
- The gas cylinders should be stored vertically, except gas cylinders with a convex bottom; these should be stored horizontally, or in a crate.
- The gas cylinders should be protected from falling or from jolts, for example, by implementing the following precautions: securing the gas cylinders or placing them in a crate.
- The gas cylinders should be stored in a well-ventilated room that is exclusively used for the storage of medicinal gases. This storage room must not contain any inflammable materials.
- Gas cylinders containing a different kind of gas, or a gas that has a different composition, should be stored separately.
- Full and empty gas cylinders should be stored separately.
- The gas cylinders must not be stored in the vicinity of sources of heat.
- Gas cylinders must be stored covered and protected against the effects of the weather.
- Close the valves of the cylinders after use.
- Return cylinder to the supplier when empty.

6.5 Nature and contents of container

Medicinal air is packaged in gas cylinders in a gaseous state and under the pressure of 200 bar (at 15°C). The cylinders are made of steel or aluminium. The valves are made of brass, steel or aluminium.

Gas cylinders with a content of (x) litres deliver (y) litres of air at 15°C and 1 bar.

| Content in litres (x) | 1 | 2 | 3 | 5 | 10 | 20 | 30 | 40 |
|------------------------------|-----------|-------------|-------------|--------------|--------------|--------------|--------------|--------------|
| Number of litres of air (y) | 196 | 393 | 589 | 982 | 1965 | 3929 | 5894 | 7858 |
| Content in litres (x) | | | | | | | | |
| | 50 | 8x40 | 8x50 | 12x40 | 12x50 | 16x40 | 16x50 | 20x50 |
| Number of litres of air (y) | 9823 | 62867 | 78584 | 94301 | 117876 | 125735 | 157168 | 196460 |

| | |
|------------------|----------------------------|
| Packaging | Available sizes (l) |
|------------------|----------------------------|

| | |
|--|---|
| Aluminium cylinder with integrated valve | 1, 2, 3, 5, 10, 20, 30, 40, 50 |
| Steel cylinder with integrated valve | 1, 2, 3, 5, 10, 20, 30, 40, 50 |
| Aluminium cylinder with yoke type valve | 1, 2, 3, 5, 10, 20, 30, 40, 50 |
| Steel cylinder with yoke type valve | 1, 2, 3, 5, 10, 20, 30, 40, 50 |
| Aluminium cylinder with threaded valve | 1, 2, 3, 5, 10, 20, 30, 40, 50 |
| Steel cylinder with threaded valve | 1, 2, 3, 5, 10, 20, 30, 40, 50 |
| Steel cylinder bundles with threaded valve | 8x40, 8x50, 12x40, 12x50, 16x40, 16x50, 20x50 |
| Aluminium cylinder bundles with threaded valve | 8x40, 8x50, 12x40, 12x50, 16x40, 16x50, 20x50 |

| Type of the valve | Outlet pressure | Remarks |
|-------------------|---|--|
| Integrated valve | 4 bar (at the socket outlet) | |
| Yoke type valve | 200 bar (when the gas cylinder is full) | Use only with a suitable reducing device |
| Threaded valve | 200 bar (when the gas cylinder is full) | Use only with a suitable reducing device |

Gas cylinders comply with the requirements of Dir. 1999/36/EC

Colour marking conforms to EN 1089-3: white body and white/black shoulder.

Valves conform to the requirements of EN ISO 10297.

Threaded valves outlets conform to NEN 3268 (NL), DIN 477 (DE), BS 341-3 (UK), NBN 226 (BE).

Yoke type valves conform to EN ISO 407.

Integrated valves conform also with EN ISO 10524-3.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Follow the instructions of your supplier, particularly:

- If the gas cylinder is visibly damaged, or if there is a suspicion of damage or exposure to extreme temperatures has occurred, the gas cylinder may not be used.
- All contact with oil, grease or hydrocarbons must be avoided.
- Only equipment suitable for use with a specific gas cylinder and that specific gas may be used.
- When opening and closing the valve of a gas cylinder, no pliers or other tools must be used so as to avoid the risk of damage.
- No modifications to the form of packaging must be made.
- In case of leakage, the valve of the cylinder should be closed immediately, if this can be performed in a safe manner. If the valve cannot be closed, the cylinder should be emptied in a safe location in the open air.
- Valves of empty gas cylinders must be closed.
- The transferring of gas under pressure is prohibited.
- Keep the container away from open fire.

- Smoking is not allowed during the use of medicinal air or in the vicinity of gas cylinders.

7 MARKETING AUTHORISATION HOLDER

SOL SpA
Via Borgazzi, 27
20900 Monza (MI)
Italy

8 MARKETING AUTHORISATION NUMBER(S)

PL 35326/0005

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

16/10/2024

10 DATE OF REVISION OF THE TEXT

16/10/2024