

Medicinal air synthetic SOL 21.75% v/v

Medicinal gas, compressed

Oxygen

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Medicinal air synthetic SOL is and what it is used for
2. What you need to know before you use Medicinal air synthetic SOL
3. How to use Medicinal air synthetic SOL
4. Possible side effects
5. How to store Medicinal air synthetic SOL
6. Contents of the pack and other information

1. WHAT MEDICINAL AIR SYNTHETIC SOL IS AND WHAT IT IS USED FOR

Medicinal air synthetic SOL is an inhalation gas and belongs to the group of medicinal gases. This medicine is used to prevent oxygen deficiency where treatment with atmospheric air is indicated.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDICINAL AIR SYNTHETIC SOL

Do not use Medicinal air synthetic SOL

There are no known situations in which this medicine cannot be used.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine.

- Before treatment with medicinal air, ensure that it is administered at atmospheric pressure.
- The administration of pressurised medicinal air may cause decompression sickness and oxygen toxicity. Decompression sickness is a disease that occurs during the transition from high pressure to normal pressure and causes headache, nausea, and confusion, and sometimes paralysis and un-consciousness (and even death).
- If medicinal air is mixed with other inhalational gases, there should be sufficient oxygen (at least 21% v/v) in this gas mixture. Therefore mixtures of medicinal air with other gases must always include additional oxygen from other sources.
- If you administer medicinal air at a high flow rate because it may feel cold.
- Medicinal air should not be used where higher than atmospheric concentrations of oxygen (>21%) would be indicated.

Other medicines and Medicinal air synthetic SOL

It is not known whether this medicine may affect the use of other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

This medicine can be used if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine does not affect the ability to drive and use machines.

3. HOW TO USE MEDICINAL AIR SYNTHETIC SOL

Dosage

The dosage depends on the clinical situation and should be adjusted to the patient's needs. Check with your doctor or pharmacist if you are not sure.

How to use Medicinal air synthetic SOL

In order to be able to use medicinal air, the high pressure in the cylinder must be reduced to the required pressure using a reducing device.

If you need to use medicinal air for a long period, it is recommended that the medicinal air is humidified.

Your healthcare professional will ensure that your medicinal air supply is suitable for your use and that the equipment has been set up correctly so that you receive the right amount of air.

This medicine is a gas for inhalation and is administered with inhaled air via a special device, such as a nasal catheter, a face mask, with a hood that fits around the head or by a tube into the windpipe (tracheotomy). The device must be used as per the manufacturer's instructions.

Any excess air leaves your body through breathing out and is mixed with the surrounding air.

If you are unable to breathe by yourself, you may receive artificial ventilation.

BEFORE USE

- Remove tamper evident seal
- Ensure connecting faces are clean
- Check sealing washer condition
- Open cylinder valve slowly
- Check for leaks

AFTER USE

- Close cylinder valve when not in use
- Close valve slowly with moderate force

Follow your supplier's instructions, particularly with regard to the following:

- The gas cylinder must not be used if it is visibly damaged or is suspected of having been damaged or exposed to extreme temperatures.
- All contact with oil, grease or other hydrocarbons (like vaseline, vaseline containing creams) must be avoided.
- Only equipment suitable for the specific type of gas cylinder and gas should be used.
- No tongs or other tools should be used to open or close the gas cylinder valve to prevent risk of damage.
- No change to the way the cylinder is packed should be made.
- In the event of leakage, the cylinder valve must be closed immediately, if this is safe to do so. If the valve cannot be closed, the cylinder must be taken to a safe place to let it empty in the open air.
- Valves of empty cylinders must be closed.
- Connections for tubes, valves, etc. must be clean and dry. If necessary, clean them according to the supplier's instructions. Do not use any solvents. Use clean, lint-free cloths for cleaning and drying.
- The siphoning of gas under pressure is not permitted.
- Smoking or naked flames are not permitted near gas cylinders.

If you use more Medicinal air synthetic SOL than you should

There are no known risks of overdose with this medicine.

If you forget to use Medicinal air synthetic SOL

Use this medicine as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

There are no known side effects.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDICINAL AIR
SYNTHETIC SOL

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the gas cylinder after “do not use after” or “EXP”. The expiry date refers to the last day of that month.

The following safety precautions must be followed when storing the gas cylinders:

- Store between -20°C and +65°C.
- Store in a vertical position. For cylinders with a rounded base, store horizontally or in a crate.
- Protect from falling or shock, by taking appropriate precautions such as securing the cylinders or placing them in a crate.
- Protect from sunlight. Store in a well ventilated room that is intended exclusively for storage of medicinal gases.
- Keep away from combustible materials.
- Gas cylinders containing different type of gas or composition should be stored separately.
- Full and empty gas cylinders should be stored separately.
- Gas cylinders must not be stored close to sources of heat.
- Store cylinders under cover and protected against the effects of weather.
- Close valves of gas cylinders after use.
- Return gas cylinders to supplier when empty.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Medicinal air synthetic SOL contains

- The active substance is oxygen 21.75% v/v
- The other ingredient is nitrogen

What Medicinal synthetic SOL looks like and contents of the pack

- Medicinal air synthetic SOL is an inhalation gas. The gas is colourless, odourless and tasteless.
- Medicinal air synthetic SOL is stored in gas cylinders 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.
- The shoulder of the cylinder is colour-coded in black and white. The colour of the cylinder body is white.

- The gas cylinders, valves and valve outlets conform to relevant EU standards.
- Gas cylinders with a capacity of (x) litres supply (y) litres of air at 15°C and 1 Bar as follows:

Content (x) in litres	1	2	3	5	10	20	30	40
Number of litres of air (y)	196	393	589	982	1956	3929	5894	7858
Content (x) in litres	50	8x40	8x50	12x40	12x50	16x40	16x50	20x50
Number of litres of air (y)	9823	62867	78584	94301	117876	125735	157168	196460
Not all pack sizes may be marketed.								

Marketing Authorization Holder

SOL S.p.A.
Via Borgazzi, 27
20900 Monza,
Italy

Manufacturer
SOL Nederland B.V.
Swaardvenstraat 11
5048 AV Tilburg
Netherlands

BTG Sprl
Zoning Ouest 15
7860 Lessines
Belgium

SOL Hellas S.A.
Thesi Paxi Patima Stefanis
19200 Kamari Boiotias
Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Lucht synthetisch medicinaal SOL
Czech Republic: Vzduch medicínální syntetický SOL
Germany: Künstliche Luft zur medizinischen Anwendung SOL
Greece: Φαρμακευτικός Συνθετικός Αέρας SOL
Ireland: Medicinal air synthetic SOL
Luxemburg: Air synthétique médicinal SOL
Spain: Aire medicinal sintético Solgroup
The Netherlands: Lucht synthetisch medicinaal SOL
United Kingdom: Medicinal air synthetic

This leaflet was last revised in 02/2016