Package leaflet: Information for the user
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.
- Absolute compliance with the safety precautions specified below is required both before and during the intake of medicinal air.
- Synthetic medicinal air is given to you using a specific equipment. If the equipment doesn't have a valve to control the pressure, there is a risk of injury from changes in air pressure called barotrauma

Safety precautions

- It must be said that air is not flammable per se but oxygen can activate combustion when there are combustible substances, such as fats (oils, lubricants) and organic substances (fabrics, wood, paper, plastic materials, etc.), as a result of a trigger (sparks, naked flame, source of ignition), or during sudden reduction in gas pressure. Hence:
- do not use either greasy creams or lipsticks;
- do not smoke;
- do not approach the cylinder with naked flames;
- do not use any electrical equipment that can issue sparks near the patients who receive medicinal air;
- do not use oils or grease on connections, taps, valve and on any material in contact with oxygen;
- never introduce air into a device that might contain combustible materials, particularly greasy materials;
- do not intervene in any way on cylinder connections, on supplying devices and on the related accessories or components;
- 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;
- avoid all contact with oil or grease;
- do not handle devices or components with hands or clothes or face soiled with grease, oil, creams and miscellaneous ointments.

Cylinders cannot be used, if there is any evident damage or a suspicion that they have been damaged or exposed to extreme temperatures.
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.

Paediatric population

There are no other warnings or precautionary measures to be observed other than those mentioned above. However, caution is needed in relation to the use in children.

Other medicines and Medicinal air synthetic SOL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No reports of interaction between this medicine and other medicines have been reported.

Medicinal air synthetic with food and alcohol
No interactions with alcohol, tobacco and foods have been observed.

Pregnancy, breast-feeding and fertility
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.
This medicine can be used if you are pregnant or breast-feeding.

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.

If you take more Medicinal air synthetic SOL than you should

It is highly unlikely that you will take more Medicinal air synthetic than you should because your doctor or nurse will monitor you during treatment.
There is no risk of overdose with Medicinal air synthetic. It is important to be aware of the risk of sudden changes in air pressure (barotrauma), especially if the synthetic medicinal air is being given through equipment that doesn't have a pressure-reducing valve.

If you forget to use Medicinal air synthetic SOL
Do not take a double dose to make up for a forgotten dose. Continue treatment at the prescribed amount.

If you stop using Medicinal air synthetic
The disease that you are taking medical compressed air for may get worse.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

There are no known side effects.

However, the following side effects may occur: decompression sickness* frequency unknown
oxygen toxicity* frequency unknown
*when administered under pressure (see also "**Warnings and precautions**")

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**	**8 × 40**	**8 × 50**	**12 × 40**	**12 × 50**	**16 × 40**	**16 × 50**	**20 x 50**
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 SpA
Via Borgazzi, 27
20900 Monza
Italy

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

SOL B S.r.l.
Zoning Ouest 15
7860 Lessines
Belgium

SOL Hellas S.A.
Thesi Stefani, ASPROPYRGOS ATTIKI,
GR-193 00, 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 medicinální 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

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