

Package leaflet:
information for the user

UK_OX_P_60_2016-10

Medical Oxygen 100%

Medicinal gas, compressed Oxygen

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

The full name of this medicine is Medical Oxygen 100 % Medicinal gas, compressed. For ease of reference it will be referred to as medicinal oxygen throughout the leaflet.

1. WHAT MEDICINAL OXYGEN IS AND WHAT IT IS USED FOR

Medicinal oxygen contains oxygen, a gas that is essential for life. Treatment with oxygen can take place under normal pressure and under high pressure.

Oxygen therapy at normal pressure (normobaric oxygen therapy)

Oxygen therapy at normal pressure can be used to treat:

- **low oxygen concentration of the blood or of a specific organ**, or to prevent this from happening
- **cluster headaches** (a specific headache with short and very severe attacks on one side of the head)

Oxygen therapy at high pressure (hyperbaric oxygen therapy)

Oxygen therapy at high pressure should only be administered by qualified healthcare professionals in order to avoid the risk of injury due to strong fluctuations in pressure.

Oxygen therapy at high pressure can be used:

- for the treatment of **serious carbon monoxide poisoning** (e.g., when the patient is unconscious)
- for the treatment of the bends (**decompression disease**)
- for the treatment of a **obstruction** in the heart or blood vessels caused by bubbles (gas or air embolism)

- for the support treatment in cases of **bone loss** after radiotherapy
- for the support **treatment in cases of dying tissue** as a result of an injury infected with gas-producing bacteria

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDICINAL OXYGEN

Do not use medicinal oxygen

• For oxygen therapy at high pressure: untreated collapsed lung (pneumothorax). Inform your doctor if you ever had a collapsed lung.

Warnings and precautions

Before you start oxygen therapy you should know the following:

- Oxygen may have harmful effects at **high concentrations**. This may cause the alveoli (tiny sacs in the lungs) to collapse which will stop the oxygen supply to the blood. This can happen when using a concentration of:
 - 100% for more than 6 hours
 - 60 to 70% after more than 24 hours
 - during the second day of the treatment at 40 to 50%
 - below 40% after more than 2 days.
- Be extra careful with administering oxygen to **new-born infants and pre-term new-born infants**. This is to minimise the risk of injury such as eye damage. The lowest possible oxygen concentration that is still effective should be used in order to achieve an adequate oxygenation. Fluctuations in oxygen saturation should be avoided.
- Be extra careful if you have **raised carbon dioxide levels in your blood**. In extreme cases this may lead to loss of consciousness.
- If you have breathing problems triggered by a reduced oxygen level in the blood you need to be closely monitored by your doctor.
- If you have ever had a collapsed lung please let your doctor know.
- If you have ever had heart failure or if you have a heart disease please let your doctor know.
- Do not under any circumstance change the concentration of the oxygen being supplied as to avoid fluctuations in oxygen saturation.

Talk to your doctor or pharmacist before using medicinal oxygen.

Oxygen therapy at high pressure

Before using oxygen therapy at high pressure tell your doctor if you have:

- **chronic obstructive pulmonary disease (COPD)**
- a **disorder of the lungs** due to the loss of elasticity of lung tissue accompanied by (serious) shortness of breath (lung emphysema)
- **infections in the upper respiratory tract**
- recent **middle ear surgery**
- had **thoracic surgery** at any time
- untreated high fever
- serious **epilepsy**
- **heart problems**
- **low of confined spaces** (claustrophobia)
- if you have a **collapsed lung** (pneumothorax) or ever have had a collapsed lung which was treated.

Oxygen therapy at high pressure should be used with caution in pregnancy and females that can be pregnant. The benefits should outweigh the risks and the use should be evaluated in for each individual patient. Whenever oxygen is used, the increased risk for spontaneous ignition should be taken into account.

Other medicines and medicinal oxygen

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

The use of medicinal oxygen may increase or decrease the desirable or undesirable effects of other medicines. Please consult your doctor or pharmacist for more information. In particular, talk to your doctor or pharmacist if you are taking:

- **Amiodarone** (a medicine used to treat cardiac arrhythmia).
- **Bleomycin** or **actinomycin** (anti-cancer medicine). These medicines can cause lung damage that may be made worse by oxygen therapy, possibly with fatal consequences.

The following medicines may increase the harmful effects of medicinal oxygen:

- **Adriamycin** (anti-cancer medicine)
- **Menadion** (a medicine used to reduce the effect of anti-coagulants)
- **Promazine, chloropromazine** and **thioridazine** (medicines used to fight serious mental disorders that cause patients to lose control over their behaviour and actions (psychosis))
- **Chloroquine** (an anti-malarial drug)
- **Corticosteroids** hormones such as cortisol, hydrocortisone, prednisolone and many others (drugs that stimulate specific parts of the nervous system)
- Furadantin and similar antibiotics.

Other effects of medicinal oxygen

- If you have been previously treated for radical **oxygen damage** to the lungs (for example in the treatment of paraquat poisoning) oxygen therapy may make this lung damage worse
- The harmful effects of oxygen may increase in patients who suffer from a **lack of vitamin C, vitamin E or glutathione** (a nutrient needed for normal function of the immune system).
- The harmful effects of oxygen may be increased by **X-rays**
- The harmful effects of oxygen may increase in patients with an **overactive thyroid**.

Medicinal oxygen with food and drink
Do not drink any alcohol during oxygen therapy. Alcohol can suppress breathing.

Pregnancy, breast-feeding and fertility

- During pregnancy, the use of oxygen under normal pressure (normobaric oxygen therapy) is permitted in low concentrations.
- Only in case of life-saving treatment, oxygen can also be used during pregnancy in high concentrations and at high pressure.
- There are no objections to the use of oxygen while breast-feeding.

Oxygen therapy at high pressure should only be used if strictly necessary if you are pregnant or can be pregnant. Please inform your treating physician or specialist in case these conditions apply to you.

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

Using medicinal oxygen does not affect your ability to drive or operate machines. However, if you feel tired after using this medicine you should not drive or operate machinery.

3. HOW TO USE MEDICINAL OXYGEN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Under no circumstances should you yourself change the oxygen concentration administered to you or your child.

Dosage

Oxygen therapy at normal pressure

(normobaric oxygen therapy)

- If the oxygen concentration of the blood or of a specific organ is too low. Your doctor will tell you for how long and how many times a day you should administer medicinal oxygen because the dosage can differ from person to person. The aim is always to use the lowest possible oxygen concentration that is still effective. However, the actual oxygen concentration for inhalation should never be less than 21%, and may be increased up to 100%.

- to treat **breathing problems** because of reduced oxygen levels in the blood (hypoxia) or as a **breathing stimulus** (e.g. in pulmonary diseases as COPD): The oxygen concentration will be kept below 28% and sometimes even lower than 24%. In the case of new-born infants, oxygen concentrations for inhalation should be kept below 40% and only in very exceptional cases raised to 100%. The lowest possible oxygen concentration that is still effective should be used in order to achieve an adequate oxygenation. Fluctuations in oxygen saturation should be avoided.

- to treat **cluster headaches**:

100% oxygen is administered at a flow rate of 7 litres a minute, for a period of 15 minutes using a facial mask. Treatment should begin when the first symptoms occur.

How to use oxygen therapy at normal pressure

- Medicinal oxygen is a gas for inhalation that is administered using special equipment, such as a nose catheter or a facial mask. Any excess oxygen leaves your body through exhalation and mixes with the ambient air (this is called a *“non-rebreathing” system*).
- If you cannot breathe independently, you will be put on artificial breathing. During anaesthesia, special equipment with rebreathing or recycling systems is used so that the exhaled air is inhaled once again (this is called a *“rebreathing” system*).
- Oxygen can also be injected directly into the bloodstream using an oxygenator. This technique is used when the blood needs to be diverted outside the body, for example in heart surgery.

How to receive oxygen therapy at high pressure

- Oxygen therapy at **high pressure** should only be administered by healthcare professionals in order to avoid the risk of injury due to strong fluctuations in pressure.
- Depending on your condition, oxygen therapy under high pressure lasts 45 to 300 minutes per treatment session. The therapy sometimes includes one or two sessions, but long-term therapy can take up to 30 sessions or more, and multiple sessions a day if necessary.
- Oxygen therapy is given in a **special pressure room**.
- Oxygen therapy at high pressure can also be provided using a close-fitting facial mask with a hood covering the head or through a tube in your mouth.

If you use more medicinal oxygen than you should

If you have used more oxygen than you should, you should contact your doctor or pharmacist immediately.

The following information is intended for healthcare professionals only:

Posology

The concentration, flow and duration of the treatment will be determined by a physician, according to the characteristics of each pathology. Hypoxemia refers to a condition where the arterial partial pressure of oxygen (PaO₂) is lower than 10 kPa (<70 mmHg). An oxygen pressure level of 8 kPa (55 / 60 mmHg) will result in respiratory insufficiency. Hypoxemia is treated by enriching the patient's inhalation air with extra oxygen.

The decision to introduce oxygen therapy depends on the degree of hypoxemia and the patient's individual tolerance level. In all cases, the objective of the oxygen therapy is to maintain a PaO₂ > 60 mm Hg (7,96 kPa) or oxygen saturation in the arterial blood ≥ 90%. If oxygen is administered diluted in another gas, the oxygen concentration in the inspired air (FiO₂) must be at least 21%.

Oxygen therapy at normal pressure (Normobaric oxygen therapy):

Administration of oxygen should be performed cautiously. The dose should be adapted to the individual needs of the patient, oxygen tension should remain higher than 8.0 kPa (or 60 mmHg) and oxygen saturation of haemoglobin should be > 90%. Regular monitoring of arterial oxygen tension (PaO₂) or pulseoxymetry (arterial oxygen saturation (SpO₂)) and clinical signs is necessary. The aim is always to use the lowest possible effective oxygen concentration in the inhaled air for the individual patient, which is the lowest dose to maintain a pressure of 8 kPa (60 mmHg)/saturation > 90 %. Higher concentrations should be administered as short as possible accompanied by close monitoring of blood gas values.

Oxygen can be administered safely in the following concentrations, for the periods indicated:

Up to 100%	less than 6 hours
60-70%	24 hours
40-50%	during the second 24-hour period

Oxygen is potentially toxic after two days in concentrations in excess of 40%.

Neonates are excluded from these guidelines because retrolental fibroplasia occurs with a much lower FiO₂. The lowest effective concentrations should be sought in order to achieve an adequate oxygenation appropriate for neonates.

- Spontaneously breathing patients:

The effective oxygen concentration is at least 24%. Normally, a minimum of 30% oxygen is administered to ensure therapeutic concentrations with a safety margin. The therapy with high oxygen concentration (> 60%) is indicated for short periods in case of serious asthmatic crisis, pulmonary thromboembolism, pneumonia and alveolitic fibrosis, etc.

A low oxygen concentration is indicated for the treatment of patients with chronic respiratory insufficiency due to a chronic obstructive upheaval of the airways or other causes.

The oxygen concentration must not be more than 28%, for some patients even 24% can be excessive.

Administration of higher oxygen concentrations (in some cases up to 100%) is possible, although when using most administration

devices it is very difficult to obtain concentrations > 60% (80% in the case of children).

The dose should be adapted to the individual needs of the patient, at flow rates ranging from 1 to 10 litres of gas per minute.

- Patients with chronic respiratory insufficiency: Oxygen must be administered at flow rates ranging from 0.5 to 2 liters/minute, rates should be adjusted on the basis of blood gas values. The effective oxygen concentration will be kept below 28% and sometimes even lower than 24% in patients suffering from breathing disorders who depend on hypoxia as a breathing stimulus.

- Chronic respiratory insufficiency resulting from Chronic Obstructive Pulmonary Disease (C.O.P.D.) or other conditions:

The treatment is adjusted on the basis of blood gas values. Arterial partial oxygen pressure (PaO₂) should be > 60 mm Hg (7,96 kPa) and oxygen saturation in the arterial blood ≥ 90%. The most common administration rate is 1 to 3 liters/minute for 15 to 24 hours/day, also covering paradoxical sleep (the most hypoxemia-sensitive period within a day).

During a stable disease period, CO₂ concentrations should monitored twice every 3-4 weeks or 3 times per month as CO₂ concentrations can increase during oxygen administration (hypercapnia).

- Patients with acute respiratory insufficiency: Oxygen must be administered at a rate ranging from 0.5 to 15 liters/minute, flow rates should be adjusted on the basis of blood gas values. In case of emergency, considerably higher doses (up to 60 liters/minute) are required in patients with severe respiratory difficulties.

- Mechanically ventilated patients:

If oxygen is mixed with other gases, the oxygen fraction in the inhaled gas mixture (FiO₂) may not fall under 21%. In practice, 30% tends to be used as the lower limit. If necessary, the inhaled oxygen fraction can be raised to 100%.

- Paediatric population: New-born infant: In new-born infant, concentrations of up to 100% can be administered in exceptional cases; however, the treatment must be closely monitored. The lowest effective concentrations should be sought in order to achieve an adequate oxygenation. As a rule, oxygen concentrations in excess of 40% in inhalation air must be avoided, considering the risk of eye damage (retinopathy) or pulmonary collapse. Oxygen pressure in the arterial blood must be closely monitored and kept below 13.3 kPa (100 mmHg). Fluctuations in oxygen saturation should be avoided. By preventing substantial fluctuations in oxygenation, the risk of eye damage can be reduced. (Also see section 4.4.)
- Cluster headache:

In the case of cluster headache, 100% oxygen is administered at a flow rate of 7 liters/minute for 15 minutes using a close-fitting facial mask. The treatment should begin in the earliest stage of a crisis.

Hyperbaric oxygen therapy:

Dosage and pressure should always be adapted to the patient's clinical condition and therapy should only be given after doctor's advice. However, some recommendations based on current knowledge are given below.

Hyperbaric oxygen therapy is done at pressures higher than 1 atmosphere (1.013 bars) between 1.4 and 3.0 atmosphere (usually anywhere between 2 and 3 atmosphere). Hyperbaric oxygen is administered in a special pressure room. Oxygen therapy at high pressure can also be given using a close-fitting

facial mask with a hood covering the head, or through a tracheal tube.

Each treatment session lasts 45 to 300 minutes, depending on the indication. Acute hyperbaric oxygen therapy may sometimes last just one or two sessions, whereas chronic therapy may take up to 30 or more sessions. If necessary, the sessions can be repeated two to three times a day.

• Carbon monoxide poisoning: Oxygen should be given in high concentrations (100%) as soon as possible following carbon monoxide poisoning until the carboxyhaemoglobin concentration has fallen below dangerous levels (around 5%). Hyperbaric oxygen (starting at 3 atmospheres) is indicated for patients with acute CO poisoning or have exposure intervals ≥24 hours. In addition, pregnant patients, patients with loss of consciousness or higher carboxyhemoglobin levels warrant hyperbaric oxygen therapy. Normobaric oxygen should not be used between multiple hyperbaric oxygen treatments as this can contribute to toxicity. Hyperbaric oxygen seems to also have potential in the delayed treatment of CO poisoning using multiple treatments of low dose of oxygen.

• Patients with decompression sickness: Rapid treatment at 2.8 atmosphere is recommended, repeated up to ten times if symptoms persist.

• Patients with air embolism:

In this case, the dosage is adapted to the patient’s clinical condition and blood gas values. The target values are: PaO2 > 8 kPa, or 60 mmHg, haemoglobin saturation > 90%.

• Patients with osteoradionecrosis:

Hyperbaric oxygen therapy in radiation injury usually consist of daily 90-120 min sessions at 2.0-2.5 atmosphere for about 40 days.

• Patients with clostridrial myonecrosis:

It is recommended that a 90-min treatment should be given at 3.0 atmosphere in the first 24h, followed by twice-daily treatments for 4-5 days, until clinical improvement is seen.

Method of administration

Normobaric oxygen therapy

Oxygen is administered through inhaled air, preferably using dedicated equipment (e.g., a nose catheter or facial mask) via this equipment, oxygen is administered with inhaled air. The gas plus any excess oxygen subsequently leaves the patient in the exhaled air, and mixes with the ambient air (“non-rebreathing” system). In many cases, during anaesthesia special systems with a rebreathing system or recycling system are used so that the exhaled air is inhaled once again (“rebreathing” system).

If the patient cannot breathe independently, artificial breathing support can be provided. In addition, oxygen can be injected into the bloodstream directly using a so-called oxygenator. The application of extracorporeal gas exchange devices facilitate oxygenation and decarboxylation without the harm associated with aggressive mechanical ventilation strategies. The oxygenator, which acts as an artificial lung, provides improved oxygen transfer and therefore, blood gas levels are kept within clinical acceptable ranges. After recovery of lung function extracorporeal blood and gas flow is reduced and eventually, stopped. This happens, for example, during cardiac surgery using a cardio-pulmonary by-pass system, as well as in other circumstances that require extracorporeal circulation including acute respiratory insufficiency.

Hyperbaric oxygen therapy

Hyperbaric oxygen therapy is administered in a specially constructed pressure room where the ambient pressure can be increased to up to three times the atmospheric pressure. Hyperbaric oxygen therapy can also be provided through a close-fitting facial mask with a hood covering the head, or through a tracheal tube.

Preparation prior to use

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

• Remove the seal from the valve and the protective cap before use
• Only equipment suitable for use with a specific gas cylinder and that specific gas may be used

• Check that the quick connector and regulator are clean and that the connections are in good condition

• Open the cylinder valve slowly - at least half a turn

• 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

• Check for leakage in accordance with the instructions accompanying the regulator. Do not try to deal with leakage from the valve or equipment yourself, other than by changing the gasket or O-ring

• In the event of leakage, close the valve and uncouple the regulator. If the cylinder continues to leak, empty the cylinder outdoor. Label defective cylinders, place them in an area intended for claims and return them to the supplier.

• For cylinders with an inbuilt pressure regulator valve, it is not necessary to use a separate pressure regulator. The inbuilt pressure regulator valve has a quick connector for connecting ‘on demand’ valves, but also a separate outlet for constant flow of gas, where the flow can be regulated.

Using the gas cylinder

• The transferring of gas under pressure is prohibited.

• Smoking and open flames are strictly forbidden in rooms where treatment with medicinal oxygen takes place.

• When the cylinder is in use it must be fixed in a suitable support.

• One should consider replacing the gas cylinder when the pressure in the bottle has dropped to a point where the indicator on the valve is within the yellow field.

• When a small quantity of gas is left in the gas cylinder, the cylinder valve must be closed. It is important that a small amount of pressure is left in the cylinder to avoid the entrance of contaminants.

• Valves of empty gas cylinders must be closed.

• After use the cylinder valve must be closed hand-tight. Depressurise the regulator or connection.

The toxic effects of oxygen vary according to the pressure of the inhaled oxygen and the duration of exposure.

At **low pressure** (0.5 to 2.0 bar) toxic effects are more likely to occur in the lungs (pulmonary region) than in the brain and spinal cord (central nervous system).

At **higher pressure**, the opposite applies.

The effects in the lungs (pulmonary region) include shortness of breath, coughing and chest pain.

The effects in the brain and spinal cord (central nervous system) include nausea, dizziness, anxiety and confusion, muscle cramps, loss of consciousness, and seizures (epileptic fits).

If you forget to use medicinal oxygen

Use the oxygen as described in the dosage section of the leaflet. Do not use a double dose to make up for a forgotten dose. This is because medicinal oxygen may be harmful in high concentrations.

If you stop using medicinal oxygen

Do not stop using this medicinal product at your own initiative. Ask your doctor or pharmacist.

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.

Treatment outside a hospital facility:

Medicinal oxygen treatment through nasal prongs may cause dry mucous membranes in the nose and mouth on account of the gas being dry.

Also read the section “If you use more Medicinal oxygen, than you should”.

Treatment in a hospital facility:

Side effects are usually seen with high concentrations (over 70%) and after prolonged treatment (at least 6–12 hours):

Common (may effect up to 1 in 10 people)

None.

Uncommon (may effect up to 1 in 100 people)

Breathing-related pain and dry cough and breathlessness.

Hyperbaric treatment

Feeling of pressure in the middle ear, rupture of the eardrum.

Rare (may effect up to 1 in 1000 people)
In newborns exposed to high oxygen concentrations: Damage to the eye, which can result in impaired vision.

Very rare (may effect up to 1 in 10000 people)

Severe difficulty breathing (respiratory distress syndrome).

Hyperbaric treatment

Anxiety or confusion and epileptic seizures. Nausea, dizziness, muscle twitching, lung damage and reversible visual changes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDICINAL OXYGEN

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 EXP. The expiry date refers to the last day of that month.

• 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 over or from mechanical shocks, for example, by fixing 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 near sources of heat. If at risk of fire - move to a safe place.

• 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.
• Warning notices prohibiting smoking and naked lights must be posted clearly in the storage area.
• Emergency services should be advised of the location of the cylinder storage.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What medicinal oxygen contains

• The active substance is oxygen, 100% v/v.
• There are no other ingredients.

What medicinal oxygen looks like and contents of the pack

Medicinal oxygen is an inhalation gas. It is supplied as a liquid or gas in a special container.

Oxygen is a colourless, tasteless and odourless gas.

In liquid state it has a blue colour.

Gaseous medicinal oxygen is stored in gas cylinders in a gaseous state and under a pressure of 200 or 300 bar (at 15°C). The cylinders are made of steel or aluminium. The valves are made of brass, steel or aluminium.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

SOL S.p.A.

via Borgazzi 27 - 20900 Monza, Italy

Manufacturer

B.T.G. Sprl

Zoning Ouest, 15 - 7860 Lessines, Belgium

Vivisol Ibérica, S.L.

C/ Yeso, 2 - Polígono Velasco

Arganda del Rey - 28500 Madrid, Spain

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

SOL Bulgaria JSC

12,Vladaiska Reka Str. - 1510 Sofia, Bulgaria

SPG - SOL Plin Gorenjska d.o.o.

Cesta železarjev 8 - 4270 Jesenice, Slovenia

SOL Technische Gase GmbH

Marie-Curie Strasse 1 - 2700 Wiener Neustadt

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SOL Hellas S.A. Thessaloniki Branch

Oreokastron Industrial Park

P.O. Box 1631, 57008 Thessaloniki, Greece

Packaging	Available sizes (l)
Aluminium cylinder with valve with integrated pressure regulation	1, 2, 5, 10, 20, 30, 50
Steel cylinder with valve with integrated pressure regulation	1, 2, 5, 10, 20, 30, 50
Aluminium cylinder with traditional or step down valve	1, 2, 5, 10, 20, 30, 50
Steel cylinder with traditional or step down valve	1, 2, 5, 10, 20, 30, 50
Steel cylinder bundles with traditional or step down valve	4x50, 8x50, 12x50, 16x50, 20x50
Aluminium cylinder bundles with traditional or step down valve	4x50, 8x50, 12x50, 16x50, 20x50

Type of the valve	Outlet pressure	Remarks
Valve with integrated pressure regulation	4 bar (at the socket outlet)	
Traditional valve	200 or 300 bar (when the gas cylinder is full)	Use only with a suitable reducing device
Step down valve	60-70 bar	For 300 bar cylinders only. 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 shoulder. Valves conform to the requirements of EN ISO 10297. Traditional valves and step down valves conform to NEN 3268 (NL), DIN 477 (DE), BS 341-3 (UK), NBN 226 (BE), EN ISO 407, ISO 5145. Valves with integrated pressure regulator conform also with EN ISO 10524-3.

Gas cylinders with a content of (x) litres contain (y) kg of gas and deliver (z) m³ of oxygen at 15°C and 1 bar when filled to 200 bar .						
Content in litres (x)	1	2	5	10	20	30
Content in kg (y)	0.288	0.577	1.44	2.88	5.77	8.65
Number of m³ of oxygen (z)	0.212	0.425	1.125	2.12	4.33	6.37
Content in litres (x)	50	4x50	8x50	12x50	16x50	20x50
Content in kg (y)	14.4	57.7	115	173	231	288
Number of m³ of oxygen (z)	10.61	42.5	85.0	127.5	170.0	212.0
Not all cylinder sizes may be marketed.						

Gas cylinders with a content of (x) litres contain (y) kg of gas and deliver (z) m³ of oxygen at 15°C and 1 bar when filled to 300 bar .						
Content in litres (x)	1	2	5	10	20	30
Content in kg (y)	0.413	0.826	2.06	4.13	8.26	12.4
Number of m³ of oxygen (z)	0.308	0.616	1.54	3.08	6.16	9.24
Content in litres (x)	50	4x50	8x50	12x50	16x50	20x50
Content in kg (y)	20.6	82.6	165	248	330	413
Number of m³ of oxygen (z)	15.4	61.6	123	185	246	308
Not all cylinder sizes may be marketed.						

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- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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6. Contents of the pack and other information

The full name of this medicine is Liquid Medical Oxygen 100 % Medicinal gas, cryogenic. For ease of reference it will be referred to as medicinal oxygen throughout the leaflet.

1. WHAT MEDICINAL OXYGEN IS AND WHAT IT IS USED FOR

Medicinal oxygen contains oxygen, a gas that is essential for life. Treatment with oxygen can take place under normal pressure and under high pressure.

Oxygen therapy at normal pressure (normobaric oxygen therapy)

Oxygen therapy at normal pressure can be used to treat:

- **low oxygen concentration of the blood or of a specific organ**, or to prevent this from happening
- **cluster headaches** (a specific headache with short and very severe attacks on one side of the head)

Oxygen therapy at high pressure (hyperbaric oxygen therapy)

Oxygen therapy at high pressure should only be administered by qualified healthcare professionals in order to avoid the risk of injury due to strong fluctuations in pressure. Oxygen therapy at high pressure can be used:

- for the treatment of **serious carbon monoxide poisoning** (e.g., when the patient is unconscious)

- for the treatment of the bends (**decompression disease**)
- for the treatment of a **obstruction** in the heart or blood vessels caused by bubbles (gas or air embolism)
- for the support treatment in cases of **bone loss** after radiotherapy
- for the support **treatment in cases of dying tissue** as a result of an injury infected with gas-producing bacteria

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDICINAL OXYGEN

Do not use medicinal oxygen

- For oxygen therapy at high pressure: untreated collapsed lung (pneumothorax). Inform your doctor if you ever had a collapsed lung.

Warnings and precautions

Before you start oxygen therapy you should know the following:

- Oxygen may have harmful effects at **high concentrations**. This may cause the alveoli (tiny sacs in the lungs) to collapse which will stop the oxygen supply to the blood. This can happen when using a concentration of:
 - 100% for more than 6 hours
 - 60 to 70% after more than 24 hours
 - during the second day of the treatment at 40 to 50%
 - below 40% after more than 2 days.
- Be extra careful with administering oxygen to **new-born infants and pre-term new-born infants**. This is to minimise the risk of injury such as eye damage. The lowest possible oxygen concentration that is still effective should be used in order to achieve an adequate oxygenation. Fluctuations in oxygen saturation should be avoided.
- Be extra careful if you have **raised carbon dioxide levels in your blood**. In extreme cases this may lead to loss of consciousness.
- If you have breathing problems triggered by a reduced oxygen level in the blood you need to be closely monitored by your doctor.
- If you have ever had a collapsed lung please let your doctor know.
- If you have ever had heart failure or if you have a heart disease please let your doctor know.
- Do not under any circumstance change the concentration of the oxygen being supplied as to avoid fluctuations in oxygen saturation.

Talk to your doctor or pharmacist before using medicinal oxygen.

Oxygen therapy at high pressure

Before using oxygen therapy at high pressure tell your doctor if you have:

- **chronic obstructive pulmonary disease (COPD)**
- a **disorder of the lungs** due to the loss of elasticity of lung tissue accompanied by (serious) shortness of breath (lung emphysema)
- **infections in the upper respiratory tract**
- recent **middle ear surgery**
- had **thoracic surgery** at any time
- untreated high fever
- serious **epilepsy**
- **heart problems**
- **feat of confined spaces** (claustrophobia)
- if you have a **collapsed lung** (pneumothorax) or ever have had a collapsed lung which was treated.

Oxygen therapy at high pressure should be used with caution in pregnancy and females that can be pregnant. The benefits should outweigh the risks and the use should be evaluated in for each individual patient. Whenever oxygen is used, the increased risk

for spontaneous ignition should be taken into account.

Other medicines and medicinal oxygen

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

The use of medicinal oxygen may increase or decrease the desirable or undesirable effects of other medicines. Please consult your doctor or pharmacist for more information. In particular, talk to your doctor or pharmacist if you are taking:

- **Amiodarone** (a medicine used to treat cardiac arrhythmia).
 - **Bleomycin** or **actinomycin** (anti-cancer medicine). These medicines can cause lung damage that may be made worse by oxygen therapy, possibly with fatal consequences.
- The following medicines may increase the harmful effects of medicinal oxygen:
- **Adriamycin** (anti-cancer medicine)
 - **Menadion** (a medicine used to reduce the effect of anti-coagulants)
 - **Promazine, chlorpromazine** and **thioridazine** (medicines used to fight serious mental disorders that cause patients to lose control over their behaviour and actions (psychosis))
 - **Chloroquine** (an anti-malarial drug)
 - **Corticosteroids** hormones such as cortisol, hydrocortisone, prednisolone and many others (drugs that stimulate specific parts of the nervous system)
 - Furadantin and similar antibiotics.

Other effects of medicinal oxygen

- If you have been previously treated for radical **oxygen damage** to the lungs (for example in the treatment of paraquat poisoning) oxygen therapy may make this lung damage worse
- The harmful effects of oxygen may increase in patients who suffer from a **lack of vitamin C, vitamin E or glutathione** (a nutrient needed for normal function of the immune system).
- The harmful effects of oxygen may be increased by **X-rays**
- The harmful effects of oxygen may increase in patients with an **overactive thyroid**.

Medicinal oxygen with food and drink
Do not drink any alcohol during oxygen therapy. Alcohol can suppress breathing.

Pregnancy, breast-feeding and fertility

- During pregnancy, the use of oxygen under normal pressure (normobaric oxygen therapy) is permitted in low concentrations.
- Only in case of life-saving treatment, oxygen can also be used during pregnancy in high concentrations and at high pressure.
- There are no objections to the use of oxygen while breast-feeding.

Oxygen therapy at high pressure should only be used if strictly necessary if you are pregnant or can be pregnant. Please inform your treating physician or specialist in case these conditions apply to you.

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

Using medicinal oxygen does not affect your ability to drive or operate machines. However, if you feel tired after using this medicine you should not drive or operate machinery.

3. HOW TO USE MEDICINAL OXYGEN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Under no circumstances should you yourself change the oxygen concentration administered to you or your child.

Dosage

Oxygen therapy at normal pressure (normobaric oxygen therapy)

- If the oxygen concentration of the blood or of a specific organ is too low. Your doctor will tell you for how long and how many times a day you should administer medicinal oxygen because the dosage can differ from person to person. The aim is always to use the lowest possible oxygen concentration that is still effective. However, the actual oxygen concentration for inhalation should never be less than 21%, and may be increased up to 100%.
- to treat **breathing problems** because of reduced oxygen levels in the blood (hypoxia) or as a **breathing stimulus** (e.g. in pulmonary diseases as COPD): The oxygen concentration will be kept below 28% and sometimes even lower than 24%. In the case of new-born infants, oxygen concentrations for inhalation should be kept below 40% and only in very exceptional cases raised to 100%. The lowest possible oxygen concentration that is still effective should be used in order to achieve an adequate oxygenation. Fluctuations in oxygen saturation should be avoided.

- to treat **cluster headaches**:

100% oxygen is administered at a flow rate of 7 litres a minute, for a period of 15 minutes using a facial mask. Treatment should begin when the first symptoms occur.

How to use oxygen therapy at normal pressure

- Medicinal oxygen is a gas for inhalation that is administered using special equipment, such as a nose catheter or a facial mask. Any excess oxygen leaves your body through exhalation and mixes with the ambient air (this is called a *“non-rebreathing” system*).
- If you cannot breathe independently, you will be put on artificial breathing. During anaesthesia, special equipment with rebreathing or recycling systems is used so that the exhaled air is inhaled once again (this is called a *“rebreathing” system*).
- Oxygen can also be injected directly into the bloodstream using an oxygenator. This technique is used when the blood needs to be diverted outside the body, for example in heart surgery.

How to receive oxygen therapy at high pressure

- Oxygen therapy at **high pressure** should only be administered by healthcare professionals in order to avoid the risk of injury due to strong fluctuations in pressure.
- Depending on your condition, oxygen therapy under high pressure lasts 45 to 300 minutes per treatment session. The therapy sometimes includes one or two sessions, but long-term therapy can take up to 30 sessions or more, and multiple sessions a day if necessary.
- Oxygen therapy is given in a **special pressure room**.

The following information is intended for healthcare professionals only:

Posology

The concentration, flow and duration of the treatment will be determined by a physician, according to the characteristics of each pathology.

Hypoxemia refers to a condition where the arterial partial pressure of oxygen (PaO₂) is lower than 10 kPa (<70 mmHg). An oxygen pressure level of 8 kPa (55 / 60 mmHg) will result in respiratory insufficiency. Hypoxemia is treated by enriching the patient’s inhalation air with extra oxygen. The decision to introduce oxygen therapy depends on the degree of hypoxemia and the patient’s individual tolerance level. In all cases, the objective of the oxygen therapy is to maintain a PaO₂ > 60 mm Hg (7,96 kPa) or oxygen saturation in the arterial blood ≥ 90%.

If oxygen is administered diluted in another gas, the oxygen concentration in the inspired air (FiO₂) must be at least 21 %.

Oxygen therapy at normal pressure (Normobaric oxygen therapy):

Administration of oxygen should be performed cautiously. The dose should be adapted to the individual needs of the patient, oxygen tension should remain higher than 8.0 kPa (or 60 mmHg) and oxygen saturation of haemoglobin should be > 90%. Regular monitoring of arterial oxygen tension (PaO₂) or pulseoxymetry (arterial oxygen saturation (SpO₂)) and clinical signs is necessary. The aim is always to use the lowest possible effective oxygen concentration in the inhaled air for the individual patient, which is the lowest dose to maintain a pressure of 8 kPa (60 mmHg)/saturation > 90 %. Higher concentrations should be administered as short as possible accompanied by close monitoring of blood gas values.

Oxygen can be administered safely in the following concentrations, for the periods indicated:

Up to 100%	less than 6 hours
60-70%	24 hours
40-50%	during the second 24-hour period

Oxygen is potentially toxic after two days in concentrations in excess of 40%.

Neonates are excluded from these guidelines because retrolental fibroplasia occurs with a much lower FiO₂. The lowest effective concentrations should be sought in order to achieve an adequate oxygenation appropriate for neonates.

- Spontaneously breathing patients: The effective oxygen concentration is at least 24%. Normally, a minimum of 30% oxygen is administrated to ensure therapeutic concentrations with a safety margin. The therapy with high oxygen concentration (> 60%) is indicated for short periods in case of serious asthmatic crisis, pulmonary thromboembolism, pneumonia and alveolitic fibrosis, etc.
- A low oxygen concentration is indicated for the treatment of patients with chronic respiratory insufficiency due to a chronic obstructive upheaval of the airways or other causes. The oxygen concentration must not be more than 28%, for some patients even 24% can be excessive. Administration of higher oxygen concentrations (in some cases up to 100%) is

possible, although when using most administration devices it is very difficult to obtain concentrations > 60% (80% in the case of children).

The dose should be adapted to the individual needs of the patient, at flow rates ranging from 1 to 10 litres of gas per minute.

- Patients with chronic respiratory insufficiency: Oxygen must be administered at flow rates ranging from 0.5 to 2 liters/minute, rates should be adjusted on the basis of blood gas values. The effective oxygen concentration will be kept below 28% and sometimes even lower than 24% in patients suffering from breathing disorders who depend on hypoxia as a breathing stimulus.

- Chronic respiratory insufficiency resulting from Chronic Obstructive Pulmonary Disease (C.O.P.D.) or other conditions: The treatment is adjusted on the basis of blood gas values. Arterial partial oxygen pressure (PaO₂) should be > 60 mm Hg (7,96 kPa) and oxygen saturation in the arterial blood ≥ 90%.

The most common administration rate is 1 to 3 liters/minute for 15 to 24 hours/day, also covering paradoxical sleep (the most hypoxemia-sensitive period within a day). During a stable disease period, CO₂ concentrations should monitored twice every 3-4 weeks or 3 times per month as CO₂ concentrations can increase during oxygen administration (hypercapnia).

- Patients with acute respiratory insufficiency: Oxygen must be administered at a rate ranging from 0.5 to 15 liters/minute, flow rates should be adjusted on the basis of blood gas values. In case of emergency, considerably higher doses (up to 60 liters/minute) are required in patients with severe respiratory difficulties.

- Mechanically ventilated patients:

If oxygen is mixed with other gases, the oxygen fraction in the inhaled gas mixture (FiO₂) may not fall under 21 %. In practice, 30% tends to be used as the lower limit. If necessary, the inhaled oxygen fraction can be raised to 100%.

- Paediatric population: New-born infant: In new-born infant, concentrations of up to 100% can be administered in exceptional cases; however, the treatment must be closely monitored. The lowest effective concentrations should be sought in order to achieve an adequate oxygenation. As a rule, oxygen concentrations in excess of 40% in inhalation air must be avoided, considering the risk of eye damage (retinopathy) or pulmonary collapse. Oxygen pressure in the arterial blood must be closely monitored and kept below 13.3 kPa (100 mmHg). Fluctuations in oxygen saturation should be avoided. By preventing substantial fluctuations in oxygenation, the risk of eye damage can be reduced. (Also see section 4.4.)

- Cluster headache:

In the case of cluster headache, 100% oxygen is administered at a flow rate of 7 liters/minute for 15 minutes using a close-fitting facial mask. The treatment should begin in the earliest stage of a crisis.

Hyperbaric oxygen therapy:

Dosage and pressure should always be adapted to the patient's clinical condition and therapy should only be given after doctor's advice. However, some recommendations based on current knowledge are given below.

Hyperbaric oxygen therapy is done at pressures higher than 1 atmosphere (1.013 bars) between 1.4 and 3.0 atmosphere (usually anywhere between 2 and 3 atmosphere). Hyperbaric oxygen is administered in a special pressure room. Oxygen therapy at high pressure can also be given using a close-fitting facial mask with a hood covering the head, or through a tracheal tube.

Each treatment session lasts 45 to 300 minutes, depending on the indication. Acute hyperbaric oxygen therapy may sometimes last just one or two sessions, whereas chronic therapy may take up to 30 or more sessions. If necessary, the sessions can be repeated two to three times a day.

- Carbon monoxide poisoning:

Oxygen should be given in high concentrations (100%) as soon as possible following carbon monoxide poisoning until the carboxyhaemoglobin concentration has fallen below dangerous levels (around 5%). Hyperbaric oxygen (starting at 3 atmospheres) is indicated for patients with acute CO poisoning or have exposure intervals ≥24 hours. In addition, pregnant patients, patients with loss of consciousness or higher carboxyhemoglobin levels warrant hyperbaric oxygen therapy. Normobaric oxygen should not be used between multiple hyperbaric oxygen treatments as this can contribute to toxicity. Hyperbaric oxygen seems to also have potential in the delayed treatment of CO poisoning using multiple treatments of low dose of oxygen.

- Patients with decompression sickness: Rapid treatment at 2.8 atmosphere is recommended, repeated up to ten times if symptoms persist.
- Patients with air embolism:

In this case, the dosage is adapted to the patient’s clinical condition and blood gas values. The target values are: PaO₂ > 8 kPa, or 60 mmHg, haemoglobin saturation > 90%.

- Patients with osteoradionecrosis:

Hyperbaric oxygen therapy in radiation injury usually consist of daily 90-120 min sessions at 2.0-2.5 atmosphere for about 40 days.

- Patients with clostridial myonecrosis:

It is recommended that a 90-min treatment should be given at 3.0 atmosphere in the first 24h, followed by twice-daily treatments for 4-5 days, until clinical improvement is seen.

Method of administration

Normobaric oxygen therapy

Oxygen is administered through inhaled air, preferably using dedicated equipment (e.g., a nose catheter or facial mask) via this equipment, oxygen is administered with inhaled air. The gas plus any excess oxygen subsequently leaves the patient in the exhaled air, and mixes with the ambient air (“non-rebreathing” system). In many cases, during anaesthesia special systems with a rebreathing system or recycling system are used so that the exhaled air is inhaled once again (“rebreathing” system).

If the patient cannot breathe independently, artificial breathing support can be provided. In addition, oxygen can be injected into the bloodstream directly using a so-called oxygenator. The application of extracorporeal gas exchange devices facilitate oxygenation and decarboxylation without the harm associated with aggressive mechanical ventilation strategies. The oxygenator, which acts as an artificial lung, provides improved oxygen transfer and therefore, blood gas levels are kept within clinical acceptable

ranges. After recovery of lung function extracorporeal blood and gas flow is reduced and eventually, stopped. This happens, for example, during cardiac surgery using a cardio-pulmonary by-pass system, as well as in other circumstances that require extracorporeal circulation including acute respiratory insufficiency.

Hyperbaric oxygen therapy

Hyperbaric oxygen therapy is administered in a specially constructed pressure room where the ambient pressure can be increased to up to three times the atmospheric pressure. Hyperbaric oxygen therapy can also be provided through a close-fitting facial mask with a hood covering the head, or through a tracheal tube.

Mobile cryogenic vessel

General

Medicinal gases must only be used for medicinal purposes. Different gas types and gas qualities must be separated from each other. Full and empty containers must be stored separately.

Never use grease, oil or similar substances for lubricating screw threads that jam or are difficult to connect.

Handle valves and devices to match with clean and grease-free (hand cream, etc.) hands. Use only standard equipment that is intended for medicinal oxygen.

Preparation for use

Use only dosing devices that are intended for medicinal oxygen.

Check that the automatic coupling or dosing device is clean, and that the gaskets are in working order. Never use tools on pressure-/ flow regulators that are intended for manual connection, as this may damage the coupling. Open the valve slowly – at least one half turn. Check for leakage in accordance with the instructions supplied with the regulator. In case of leakage, the valve must be closed and the regulator disconnected. Label defective vessels, store them separately and return them to the supplier.

Use

Smoking and open flames are strictly forbidden in rooms where oxygen therapy is being carried out.

Close down the apparatus in the event of fire or if it is not being used.

Carry to safety in the event of fire.

Larger vessels must be transported by means of vehicles meant for this purpose. Pay special attention to connected devices which should not be accidentally loosened. When the vessel is empty, the gas flow is dropping. Close the exit valve and remove any couplings after the pressure has been released.

Mobile cryogenic cistern and fixed cryogenic vessels.

Only the gas supplier may handle these vessels.

• Oxygen therapy at high pressure can also be provided using a close-fitting facial mask with a hood covering the head or through a tube in your mouth.

If you use more medicinal oxygen than you should

If you have used more oxygen than you should, you should contact your doctor or pharmacist immediately.

The toxic effects of oxygen vary according to the pressure of the inhaled oxygen and the duration of exposure.

At **low pressure** (0.5 to 2.0 bar) toxic effects are more likely to occur in the lungs (pulmonary region) than in the brain and spinal cord (central nervous system). At **higher pressure**, the opposite applies. The effects in the lungs (pulmonary region) include shortness of breath, coughing and chest pain.

The effects in the brain and spinal cord (central nervous system) include nausea, dizziness, anxiety and confusion, muscle cramps, loss of consciousness, and seizures (epileptic fits).

If you forget to use medicinal oxygen

Use the oxygen as described in the dosage section of the leaflet. Do not use a double dose to make up for a forgotten dose. This is because medicinal oxygen may be harmful in high concentrations.

If you stop using medicinal oxygen

Do not stop using this medicinal product at your own initiative. Ask your doctor or pharmacist.

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.

Treatment outside a hospital facility:

Medicinal oxygen treatment through nasal prongs may cause dry mucous membranes in the nose and mouth on account of the gas being dry.

Also read the section “If you use more Medicinal oxygen, than you should”.

Treatment in a hospital facility:

Side effects are usually seen with high concentrations (over 70%) and after prolonged treatment (at least 6–12 hours):

Common (may effect up to 1 in 10 people)

None.

Uncommon (may effect up to 1 in 100 people)

Breathing-related pain and dry cough and breathlessness.

Hyperbaric treatment
Feeling of pressure in the middle ear, rupture of the eardrum.

Rare (may effect up to 1 in 1000 people)
In newborns exposed to high oxygen concentrations: Damage to the eye, which can result in impaired vision.

Very rare (may effect up to 1 in 10000 people)
Severe difficulty breathing (respiratory distress syndrome).

Hyperbaric treatment

Anxiety or confusion and epileptic seizures.

Nausea, dizziness, muscle twitching, lung damage and reversible visual changes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDICINAL OXYGEN

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 vessel/cistern after EXP. The expiry date refers to the last day of that month.

Keep the vessel/cistern in a well-ventilated area within a temperature range of -20°C and +50°C.

Keep away from inflammable and combustible materials and sources of heat or open fire. If at risk of fire – move to a safe place. Do not smoke near the vessel/cistern. The transport must be conducted in accordance with international regulations for transporting dangerous materials. Avoid any contact with oil, grease or hydrocarbons.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What medicinal oxygen contains

- The active substance is oxygen, 100% v/v.
- There are no other ingredients.

What medicinal oxygen looks like and contents of the pack

Medicinal oxygen is an inhalation gas. It is supplied as a liquid or gas in a special container.

Oxygen is a colourless, tasteless and odourless gas.

In liquid state it has a blue colour.

Liquid medicinal oxygen is packed in mobile cryogenic vessels. Mobile cryogenic vessels are made of an outer and an inner vessel of stainless steel with a vacuum insulation layer in between and fitted with dedicated filling port and withdrawal hose connection. The valves are made of brass, stainless steel and/or bronze and are specially designed for low temperatures.

These vessels contain oxygen in the liquid state at very low temperature.

The content of the vessels varies from 10 to 1100 litres.

Each litre of liquid oxygen delivers 853 litres of oxygen gas at 15°C and 1 bar.

Vessel content in litres	Capacity for liquid oxygen in litres	Equivalent amount of gaseous oxygen in m³ at 15°C and 1 atm
10	10	8,53
<i>to</i>		
1100	1100	938,3
Not all vessel sizes may be marketed		

Liquid medicinal oxygen is packed in mobile cryogenic cisterns and fixed cryogenic vessels.

Mobile cryogenic cisterns are made of an outer and an inner enclosure of stainless steel. The valves are made of brass, stainless steel and/or bronze and are specially designed for low temperatures. These cisterns contain oxygen in the liquid state at very low temperature. The content of the cisterns varies from 9000 to 26000 litres. Each litre of liquid oxygen delivers 853 litres of oxygen gas at 15°C and 1 bar.

Cistern content in litres	Capacity for liquid oxygen in litres	Equivalent amount of gaseous oxygen in m³ at 15°C and 1 atm
9000	9000	7677
<i>to</i>		
26000	26000	22178
Not all cistern sizes may be marketed		

Fixed cryogenic vessels are special steel tanks with a double wall separated by a high vacuum. The valves are made of brass, stainless steel and/or bronze and are specially designed for low temperatures. These vessels contain oxygen in the liquid state at very low temperature. The content of the vessels ranges up to 50000 litres. Each litre of liquid oxygen delivers 853 litres of oxygen gas at 15°C and 1 bar.

Vessel content in litres	Capacity for liquid oxygen in litres	Equivalent amount of gaseous oxygen in m³ at 15°C and 1 atm
Up to 50000 litres	50000 litres	42650
Not all vessel sizes may be marketed		

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

SOL S.p.A.

via Borgazzi 27

20900 Monza, Italy

Manufacturer

Liquid Medical Oxygen (mobile cryogenic vessels)

B.T.G. Sprl

Zoning Ouest, 15

7860 Lessines, Belgium

or

Vivisol Ibérica, S.L.

C/ Yeso, 2 - Poligono Velasco

Arganda del Rey

28500 Madrid, Spain

or

SOL Hellas S.A.

Thesi Paxi Patima Stefanis

19200 Kamari Boiotias, Greece

or

SOL Bulgaria JSC

12,Vladaiska Reka Str.

1510 Sofia, Bulgaria

or

SPG - SOL Plin Gorenjska d.o.o.

Cesta železarjev 8

4270 Jesenice , Slovenia

or

SOL Hellas S.A. Thessaloniki Branch

Oreokastron Industrial Park

P.O. Box 1631, 57008 Thessaloniki, Greece

Liquid Medical Oxygen (mobile cryogenic cisterns and fixed cryogenic vessels)

SOL S.p.A.

Zoning Industriel de Feluy - Zone B

7180 Seneffe, Belgium

or

SPG - SOL Plin Gorenjska d.o.o.

Cesta železarjev 8

4270 Jesenice , Slovenia

or

SOL Hellas S.A.

Thesi Paxi Patima Stefanis

19200 Kamari Boiotias, Greece

or

SOL Bulgaria JSC

12,Vladaiska Reka Str.

1510 Sofia, Bulgaria

or

SOL Bulgaria JSC

South Industrial Zone

Complex Agropolychim AD

9160 Devnya, Bulgaria

or

SOL Hellas S.A. Thessaloniki Branch

Oreokastron Industrial Park

P.O. Box 1631, 57008 Thessaloniki, Greece

This medicinal product is authorised in the

Member States of the EEA under the following names:

Belgium: Oxygène Médicinal Liquide B.T.G. -

Oxygène Médicinal Liquide SOL

Bulgaria: Медицински кислород, течен SOL

Czech Republic: Kyslík medicijnální kapalný

SOL 100% Medicijnální plyn, kryogenní

Greece: Φαρμακευτικό Οξυγόνο σε υγρή

μορφή SOL

Hungary: Oxigén SOL - Oxigén BTG

Luxemburg: Oxygène Médicinal Liquide

B.T.G. - Oxygène Médicinal Liquide SOL

Portugal: Oxygénio medicinal líquido SOL

Romania: Oxigen SOL

Slovakia: Medicijnálny kyslík kvapalný SOL

Slovenia: Medicinski kisik SOL 100%

medicinski plin, kriogenski

Spain: Oxígeno medicinal líquido Solspa -

Oxígeno medicinal líquido Solgroup

The Netherlands: Zuurstof Medicaaal

Vloeibaar SOL

UK: Liquid Medical Oxygen

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