PACKAGE LEAFLET: INFORMATION FOR THE USER

Medical Oxygen 100% medicinal gas, compressed
Liquid Medical Oxygen 100% medicinal gas, cryogenic
Liquid Medical Oxygen 100 % medicinal gas, cryogenic
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 other. 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 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 and 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

Oxygen at a pressure greater than atmospheric pressure (Hyperbaric Oxygen Therapy) must not be used in cases of untreated/undrained pneumothorax. A pneumothorax is due to the accumulation of air in the thoracic cavity between the two pulmonary membranes. If you have ever had a pneumothorax, please let your doctor know.

Warnings and precautions

Before you start oxygen therapy you should know the following:

- Oxygen may have harmful effects at **high concentrations.** This may cause pulmonary damages (collapse of the alveoli, inflammation of the lungs) which will obstruct the oxygen supply to the blood.
- If you have a severe chronic obstructive pulmonary disease (COPD) with subsequent deficiency in blood oxygenation, the flow rate of oxygen will be low. The doctor will adapt the appropriate flow rate of oxygen therapy.
- Be extra careful with administering oxygen to **new-born infants and pre-term new-born infants**. This is to minimise the risk of adverse events such as eye damage. The lowest possible oxygen concentration that is still effective should be used in order to achieve an adequate oxygenation.
- Be extra careful if you have **raised carbon dioxide levels in your blood** which neutralises the effects of oxygen. If you have breathing problems triggered by a reduced oxygen level in the blood or if you are taking strong pain killers, you need to be closely monitored by your doctor.
- If you have ever had a lung injury please let your doctor know.

Talk to your doctor or pharmacist before using medicinal oxygen.

Hyperbaric Oxygen therapy

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

- **Psychiatric problems** (anxiety, psychosis)
- **Fear of confined spaces** (claustrophobia)
- **Diabetes** (high glucose levels in your blood); due to the risk of hypoglycaemia, blood sugar should be measured between two hyperbaric therapies
- **Respiratory disorders**
- If you have ever had a **pneumothorax** which is an accumulation of air or gas in the thoracic cavity between the two pulmonary membranes
- **Heart problems**
- **High blood pressure**
- **Eye problems**
- **Ear, nose and throat disorders**

Children

In pre-term and new-born infants, oxygen therapy may lead to eye damage (retinopathy of prematurity). The doctor will determine the appropriate oxygen concentration to be administered to insure the optimal treatment for your baby.

Whenever oxygen is used, the increased risk of fire 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.
If you are taking or have been prescribed bleomycin (to treat cancer), amiodarone (to treat heart disease), nitrofurantoin (to treat infection), please advise your doctor prior to using oxygen, as there is a possibility of toxic effects to the lungs.
Previous pulmonary damage caused by the pesticide Paraquat may be exacerbated by oxygen. In case of Paraquat intoxication, oxygen supplementation should be avoided as far as possible.

The use of medicinal oxygen may increase or decrease the desirable or undesirable effects of other

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, oxygen under normal pressure (normobaric oxygen therapy). may be administered only if necessary.
- There are no objections to the use of oxygen while breast-feeding.

Oxygen therapy at high pressure (hyperbaric oxygen therapy) 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 any medicine.

Driving and using machines
Using medicinal oxygen at normal pressure (normobaric oxygen therapy) does not affect your ability to drive or operate machines. After oxygen therapy at high pressure (hyperbaric oxygen therapy) you may experience sight and hearing disorders which can influence the ability to drive and using machines.

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 supplied through a so-called 'oxygenator' directly to the blood in cases of, among other things, cardiac surgery with a heart–lung machine, and in other conditions that require extracorporeal circulation

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 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 ringing in ears, hearing and sight disorders, nausea, dizziness, anxiety and confusion, localised muscle cramps (around eyes, mouth and forehead), loss of consciousness, and seizures (epileptic fits).

Ocular effects include blurred vision and reduced peripheral vision ("tunnel vision").

In case of oxygen poisoning due to hyperoxia, oxygen therapy should be reduced or, if possible, interrupted and symptomatic treatment initiated.

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.

Safety advice on the use of medicinal oxygen
Oxygen is an oxidising product and promotes combustion. There must be no smoking or open flames(e.g. pilot lights, cookers, oven, gas fire, sparkles, candles …) in rooms where medicinal oxygen is used, as it increases the risk of fire.
Handle carefully the cylinder. Ensure that the gas cylinder is not dropped or exposed to knocks

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.

Very common (may affect more than 1 in 10 people)
With normobaric treatment: In newborns exposed to high oxygen concentrations: Damage to the eye, which can result in impaired vision.
With hyperbaric treatment: ear pain, myopia, barotrauma (injury caused to body tissues or organs by a change in pressure).

Common (may affect up to 1 in 10 people)
With hyperbaric treatment: Convulsions

Uncommon (may affect up to 1 in 100 people)

With normobaric treatment: lung collapse (atelectasis).
With hyperbaric treatment: Rupture of the eardrum

Rare (may affect up to 1 in 1000 people)
With hyperbaric treatment: breathlessness, abnormally low blood sugar level in diabetic patients.

Not known (frequency cannot be estimated from the available data)
With normobaric treatment: Pulmonary toxicity, aggravation of the excess carbon dioxide in the blood (hypercapnia), mucosal dryness, local irritation and inflammation of the mucosa.
With hyperbaric treatment: breathing difficulty, involuntary muscular contraction, vertigo, audition impairment, acute serous otitis, noise or ringing in the ears (tinnitus), sickness, abnormal behaviour, decrease in peripheral vision, visual changes, clouding of the lens (cataract).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. 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 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/vessel/cistern after EXP. The expiry date refers to the last day of that month.

Gaseous medicinal oxygen
- 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.

Liquid medicinal oxygen
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.

Gaseous medicinal oxygen

Gaseous medicinal oxygen is stored in gas cylinders in a gaseous state and under a pressure of 150, 200 or 300 bars (at 15°C). The cylinders are made of steel or aluminium. The valves are made of brass, steel or aluminium.

Packaging	Available sizes (l)*
Aluminium cylinder with valve with integrated pressure regulation	1, 2, 3, 5, 7, 8, 10, 11, 20, 30, 40, 47, 50
Steel cylinder with valve with integrated pressure regulation	1, 2, 3, 5, 7, 8, 10, 11, 20, 30, 40, 47, 50
Aluminium cylinder with traditional or step-down valve	1, 2, 3, 5, 7, 8, 10, 11, 20, 30, 40, 47, 50
Steel cylinder with traditional or step down valve	1, 2, 3, 5, 7, 8, 10, 11, 20, 30, 40, 47, 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

*7l, 40l and 47l available for 150 bar filling pressure only.

Type of the valve	Outlet pressure	Remarks
Valve with integrated pressure regulation	4 bars (at the socket outlet)	
Traditional valve	150, 200 or 300 bars (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) m^3 of oxygen at 15°C and 1 bar when filled to 150 bar.

Content in litres (x)	*1*		*2*	*5*	*7*	*10*	*20*	*30*	*40*	*47*	*50*
Content in kg (y)	*0.217*		*0.434*	*1.086*	*1.52*	*2.17*	*4.34*	*6.51*	*8.69*	*10.21*	*10.86*
Number of m³ of oxygen (z)	0.160		0.321	0.80	1.12	1.60	3.21	4.81	6.41	7.53	8.02

Content in litres (x)		*4x50*	*8x50*	*12x50*	*16x50*	*20x50*
Content in kg (y)		*43.4*	*86.8*	*130*	*174*	*217*
Number of m³ of oxygen (z)		32.1	64.1	96.2	128.2	160.3

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*	*3*	*5*	*8*	*10*	*11*	*20*	*30*	*40*
Content in kg (y)	*0.288*	*0.577*	*0.86*	*1.44*	*2.30*	*2.88*	*3.17*	*5.77*	*8.65*	11.5
Number of m³ of oxygen (z)	0.212	0.425	0.637	1.125	1.70	2.12	2.33	4.33	6.37	8.49

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	

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.

Liquid medicinal oxygen

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
to		
1,100	1,100	938.3

Not all vessel sizes may be marketed.

Liquid medicinal oxygen
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
9,000	9,000	7,677
to		
26,000	26,000	22,178

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 50,000 litres	50,000 litres	42,650

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
Gaseous medicinal oxygen
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

SOL S.p.A.
Via Acquaviva, 4
26100 Cremona
Italy

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
Austria

SOL Hellas S.A. – Thessaloniki Branch
Oreokastron Industrial Park
P.O. Box 1631
57008 Thessaloniki
Greece

Dolby Medical Home Respiratory Care Limited
Unit 18, Arkwright Road Industrial Estate
Arkwright Road
BEDFORD
MK42 0LQ
United Kingdom

Dolby Medical Home Respiratory Care Limited
Unit 2,
Broadleys Road,
Springkerse Industrial Estate,
Stirling.
FK7 7ST
United Kingdom

SOL Bulgaria EAD
South industrial zone, complex Agropolichim AD
9160 Devnja
Bulgaria

Sol France, sucursal España (SOLFSE)
Calle Telégraf, s/n, Nt.17-19,
Polígono Industrial Sota el Molí,
08160 Montmeló, (Barcelona), SPAIN

The Irish Company Oxygen ltd.
Waterfall Road, Cork, T12 PP40, Ireland

SOL Hungary Kft.
Mechwart Andràs utca 6.
Dunaharaszti, 2330, Hungary

TAE - Technika Aeria Ellados
Sindos, Industrial zone Sindos
12th km Thessaloniki-Edessa,
Thessaloniki, GR-570 08,
Greece.

TAE - Technika Aeria Ellados
Thesi Stefani,ASPROPYRGOS
ATTIKI, R-193 00, Greece

Liquid medicinal oxygen (mobile cryogenic vessels)
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

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 Hellas S.A. – Thessaloniki Branch
Oreokastron Industrial Park
P.O. Box 1631
57008 Thessaloniki
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Dolby Medical Home Respiratory Care
Limited Unit 18, Arkwright Road Industrial
Estate Arkwright Road
BEDFORD
MK42 0LQ
United Kingdom

Dolby Medical Home Respiratory Care
Limited Unit 2,
Broadleys Road,
Springkerse Industrial
Estate, Stirling
FK7 7ST
United Kingdom

SOL Bulgaria EAD
South industrial zone, complex Agropolichim
AD 9160 Devnja
Bulgaria

Sol France, sucursal España
(SOLFSE) Calle Telégraf, s/n, Nt.17-
19,
Polígono Industrial Sota el Molí,
08160 Montmeló, (Barcelona),
SPAIN

The Irish Company Oxygen ltd.
Waterfall Road, Cork, T12 PP40,
Ireland

TAE - Technika Aeria
Ellados Sindos, Industrial
zone Sindos 12th km
Thessaloniki-Edessa,
Thessaloniki, GR-570 08,
Greece.

TAE - Technika Aeria Ellados
Thesi Stefani,ASPROPYRGOS
ATTIKI, GR-193 00, Greece

Liquid medicinal oxygen (mobile cryogenic cisterns and fixed cryogenic vessels)

SOL spa
Zoning Industriel de Feluy –
Zone B 7180 Seneffe
Belgium

SPG - SOL Plin Gorenjska d.o.o.
Cesta železarjev 8
4270
Jesenice
Slovenia

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

SOL Bulgaria JSC
12,Vladaiska Reka
Str. 1510 Sofia
Bulgaria

SOL Bulgaria JSC
South Industrial
Zone
Complex Agropolychim
AD 9160 Devnya
Bulgaria

SOL Hellas S.A. – Thessaloniki Branch Oreokastron Industrial ParkP.O. Box 1631
57008
Thessaloniki
Greece

Sol France, sucursal España
(SOLFSE) Calle Telégraf, s/n, Nt.17-
19,
Polígono Industrial Sota el Molí,
08160 Montmeló, (Barcelona),
SPAIN

TAE - Technika Aeria
Ellados Sindos, Industrial
zone Sindos 12th km
Thessaloniki-Edessa,
Thessaloniki, GR-570 08,
Greece.

Technical Gases Greece
S.A., Sximatari,
59th km Athens-Lamia National Road, Viotia,
32009, 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 - Oxygène Médicinal Gazeux B.T.G.
Bulgaria : Медицински кислород, течен SOL - Медицински кислород, газообразен SOL
Czech Republic : Kyslík medicinální plynný SOL 100% Medicinální plyn, stlačený
Cyprus: Φαρμακευτικό Οξυγόνο σε υγρή μορφή SOL - Φαρμακευτικό Οξυγόνο σε αέρια μορφή SOL
Greece: Φαρμακευτικό Οξυγόνο σε υγρή μορφή SOL - Φαρμακευτικό Οξυγόνο σε αέρια μορφή SOL
Hungary : Oxigén SOL - Oxigén BTG - Oxigén SOL
Ireland: Liquid Medical Oxygen– Medical Oxygen
Luxemburg: Oxygène Médicinal Liquide B.T.G. - Oxygène Médicinal Liquide SOL - Oxygène Médicinal Gazeux B.T.G.
Portugal: Oxygénio medicinal liquid SOL - Oxygénio medicinal gasoso SOL
Romania: Oxigen SOL - Oxigen SOL
Slovakia: Medicinálny kyslík kvapalný SOL- Medicinálny kyslík plynný SOL
Slovenia: Medicinski kisik SOL 100% medicinski plin, kriogenski - Medicinski kisik SOL 100% medicinski plin, stisnjeni
Spain: Oxígeno medicinal líquido Solspa - Oxígeno medicinal líquido Solgroup - Oxígeno medicinal gas Solgroup
The Netherlands: Zuurstof Medicinaal Vloeibaar SOL
UK: Liquid Medical Oxygen– Medical Oxygen

This leaflet was last revised in 04/2024

The following information is intended for healthcare professionals only:

<u>Posology</u>
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 (PaO_2) 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 PaO_2 > 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 (FiO_2) must be at least 21%.

<u>Oxygen therapy at normal pressure (Normobaric oxygen therapy):</u>
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 (PaO_2) or pulsoxymetry (arterial oxygen saturation (SpO_2)) 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 FiO_2.

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 (PaO_2) 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, CO_2 concentrations should monitored twice every 3-4 weeks or 3 times per month as CO_2 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 (FiO_2) 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: PaO_2 > 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.

Gaseous medicinal oxygen
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.

Liquid medicinal oxygen
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.