## Medical Oxygen <br> 100\% medicinal gas, compressed

## Read all of this leaflet carefully before you

 start using this medicine because it- Keep this leaflet. You may need to read
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 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 See section 4 .


## What is in this leaflet

1. What medicinal oxygen is and what it is
2. What medicinal oxygen is and what it is
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2 What you need to know before you use
3. What you
medicinal oxygen
4. How to use medicinal oxygen
5. Possible side effects
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7. Contents of the pack and othe

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

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

 WHAT IT IS USED FORMedicinal oxygen contains oxygen, a gas that
is essential for life. Treatment with oxygen can is essential for life. Treatment with oxygen can 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

Cluster headaches (a specific headache with short and very severe attacks on one side of the head)

## Oxygen therapy at high pres (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 an obstruction in the (gast or air embolism) (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 ducing bacteria

## 2. WHAT YOU NEED TO KNOW BEFORE YOU

 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 accumulation of air in the thoracic cavity between the two pulmonary membranes. If you have ever had a pneumothorax, please let your doctor know.
## recautions <br> Before you start oxygen therapy you should

 now the following:Oxygen may have harmful effects at high
concentrations. This may caus camcentrations. This may cause pulmonary of the lungs) which will obstruct the oxygen
supply to the blood.
If you have a severe chronic obstructive
pulmonary disease (COPD) with subsequ pulmonary disease ( Oxygenation, the flow rate
deficiency in blood oxy of oxygen will be low. The doctor will adapt the appropriate flow rate of oxygen therapy.
Be extra careful with administering oxyg Be extra careful with administering oxygen to
new-born infants and pre-term new-born 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. 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
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 taking strong pain
closely monstored by your doctor.
If you have ever had a lung injury please let
your doctor know. your doctor know
Talk to your doctor or pharmacist before using medicinal oxygen.
Hyperbaric Oxygen therapy
Before using oxygen therapy at high pressure tell

- 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
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
Eye problems
Ear, nose and throat disorders
Children
In pre-term and new-born infants, oxygen herapy 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. re ignition should be taken into account.
Other medicines and medicinal oxygen
Tell your doctor or pharmacist if you are taking, ave recently taken or might take any other edicines
you are taking or have been prescribed heart disease (to treat cancer), amiodarone (to treat 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 supplementation should be avoided as far as possible.


## Medicinal oxygen with food and drink

 Do not drink any alcohol during oxygen Pregnancy, breast-feedi Pregnancy, breast-feeding and fertility - During pregnancy, oxygen under normalpressure (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 oxygen therapy) should only be used if strictly necessary if you are pregnant or can be
pregnant. Please inform your treating physicia or specialist in case these conditions apply to
you. $\begin{aligned} & \text { If you are pregnant or breast-feeding, think you }\end{aligned}$ may be pregnant or are planning to tave a baby, 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 hearing disorders which can
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
old you. Check with your doctor or pharmacist $i$ 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 alway to use the lowest possible oxygen
concentration that is still effective. However, should never be less than $21 \%$, and may be increased up to $100 \%$.
to treat breathing problems because of educed 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 e case of new-born infants, oxygen concentrations for inhalation should be kept below $40 \%$ and only in very exceptional cases aised to $100 \%$.
he lowest possible oxygen concentration tha achieve an adequate oxygenation.
Fluctuations in oxygen saturation should be
avoided. avoided.
to treat cluster headaches:
$100 \%$ oxygen is administered at a flow rate o
7 litres a minute, for a period of 15 minutes using a facial mask. Treatment should begin when the first symptoms occur.
- Medicinal oxygen is a gas for inhalation hat is administered using special facial mask. Any excesse catheter or your body through exhalation and mixe with the ambient air (this is called a "non-rebreathing" system)
If you cannot breathe independently, you anaesthesia, special equipment with ebreathing or recycling systems is used so hat the exhaled air is inhaled once again this is called a "rebreathing" system). so-called 'oxygenator' directly to the blood in cases of, among other things, cardiac surgery with a heart-lung machine, and in ther conditions that require extracorporeal circulatio


## How to re

Oxygen therapy at high pressure should rofessioministered by healthcare njury due to strong fluctuations in risk pessure.
Depending on your condition, oxygen therapy under high pressure lasts The therapy sometimes includes ons or he therapy son put lem take up to 30 sessions or more, and multiple sessions a day if necessary Oxygen therapy is given in a specia pressure room.
oxygen therapy at high pressure can also
be provided using a close-fitting facial be provided using a close-fiting 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 contac 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 a spinal cord (central nervous system). At higher pressure, the opposite applies.
The effects in the lungs (pulmonay region The effects in the lungs (pulmonary region) chest pain.
The effects in the brain and spinal cord (central nervous system) include ringing ears, hearing and sight disorders, nausea, dizziness, anxiety and confusion, localised muscle cramps(around eyes, mouth and seizures (epileptic fits).
Ocular effects include blurred vision and reduced peripheral vision ("tunnel vision"). In case of oxygen poisoning due to hyperoxia, 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 because medicinal oxygen may be harmful in
high concentrations.

If you stop using medicinal oxygen Do not stop using this medicinal product at pharmacist.

## The foilowing information is in healthcare professionals only:

## Posology

The concentration, flow and duration of the according to the characteristics of each
pathol pathology.
Hypoxemia
Hypoxemia refers to a condition where the
arterial partial pressure arterial partial pressure of oxygen $\left(\mathrm{PaO}_{2}\right)$ is lowe
than $10 \mathrm{kPa}(<70 \mathrm{mmHg})$. An oxygen pressure level of $8 \mathrm{kPa}(55 / 60 \mathrm{mmHg})$ will result in respiratory insufficiency.
Hypoxemia is treated by enriching the patient's inhalation air with extra oxygen. depends on the degree of hypoxemia and th patient's individual tolerance level. In all cases, the objective of the oxygen therapy
is to maintain a $\mathrm{PaO}_{2}>60 \mathrm{~mm} \mathrm{Hg}(7,96 \mathrm{kPa})$ or is to maintain a $\mathrm{PaO}_{2}>60 \mathrm{~mm} \mathrm{Hg}(7,96 \mathrm{kPa})$ or
oxygen saturation in the arterial blood $\geq 90 \%$. If oxygen is administered diluted in another gas,
the oxygen concentration in the inspired air ( $\mathrm{FiO}_{2}$ ) the oxygen concentrat.
must be at least $21 \%$.
Oxygen therapy at normal pressur
Normobaric oxygen herapy).
cautiously. The dose should be ady performed individual needs of the patient, oxygen tension should remain higher than 8.0 kPa (or 60 mmHg ) and oxygen saturation of haemoglobin should
$>90 \%$. Regular monitoring of arterial oxygen tension $\left(\mathrm{PaO}_{2}\right)$ or pulsoxymetry (arterial oxygen saturation ( $\mathrm{SpO}_{2}$ ) and clinical signs is necessar 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 $(60 \mathrm{mmHg}) /$ saturation $>90 \%$. Higher concentrations should be administered as short as possible accom
blood gas values.
Oxygen can be administered safely in the following
indicated
$\begin{array}{ll}\text { Up to } 100 \% & \text { less than } 6 \text { hours } \\ 60-70 \% & 24 \text { hours }\end{array}$
$40-50 \%$ ll $\begin{aligned} & \text { during the second } 24 \text {-hour } \\ & \text { period }\end{aligned}$
Oxygen is potentially toxic after tw
concentrations in excess of $40 \%$.
Neonates are excluded from these guideline Neonates are excluded from these guidelines
because retrolental fibroplasia occurs with a much lower $\mathrm{FiO}_{2}$. The lowest effective concentrations should be sought in order to neonates.

- Spontaneously breathing patients:

The effective oxygen concentration is at leas $24 \%$. 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 thromboembolis
A low oxygen concentration is indicated for the reatment of patients with chronic respiratory insufficiency due to a chronic obstructive upheaval of the airways or other causes. he oxygen concentration must not be more
than $28 \%$, for some patients even $24 \%$ can be xcessive.
Administration of higher oxygen concentrations (in some cases up to 100\%) is administration devices it is very diffic
obtain concentrations > $60 \%(80 \%$ in the case of children).
he dose should be adapted to the anvidual needs of the patient, at flow rates Patients with chronic respiratory
insufficiency:
xygen must be administered at flow rates anging from 0.5 to 2 liters/minute, rates hould be adjusted on the basis of blood as values. The effective oxygen mentration will be kept below $28 \%$ and suffering from breathing disorders who
epend on hypoxia as a breathing stimulus. Chronic respiratory insufficiency resulting
rom Chronic Obstructive Pulmonary isease (C.O.P.D.) or other conditions: The treatment is adjusted on the basis of bood gas values. Arterial partial oxygen .96 kPa ) and myg arterial blood $\geq 90 \%$.
The most common administration rate is to 3 liters/minute for 15 to 24 hours/day lso covering paradoxical sleep (the most During a stable disease period, $\mathrm{CO}_{2}$ concentrations should monitored twice very 3-4 weeks or 3 times per month as xygen administration (hypercapnia) oxygen administration (hypercapnia). Oxygen must be administered at a rate anging from 0.5 to 15 liters/minute, flow lood gas values. In case of emergency, lood gas values. In case of emergency, 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
$\mathrm{F}_{\mathrm{FiO}}^{2}$ ) may not fall under $21 \%$. In practice,
$30 \%$ tends to be used as the lower limit. necessary, the inhaled oxygen fraction
be raised to $100 \%$. Pe raised to $100 \%$.
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 achieve an adequate oxygenation. As a rule, oxygen concentrations in excess of $40 \%$ in nhalation air must be avoided, considering
he risk of eye damage (retinopathy) or pulmonary collapse. Oxygen pressure in the arterial blood must be closely monitored and ept below $13.3 \mathrm{kPa}(100 \mathrm{mmHg})$
luctuations in oxygen saturation should be voided. By preventing substantial damage can be reduced. (Also see section 4.4.)
In the case of cluster headache, $100 \%$
xygen is administered at a flow rate of 7 liters/minute for 15 minutes using a close-fititing facial mask. The treatment or yperbaric 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 ecommendations based on curren 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 3 (usually anywhere between 2 and


Safety advice on the use of medicinal oxygen
Oxygen is an oxidising product and promotes pen flames $($ here must be no smoking or re, 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
nocks.
f you have any further questions on the use of
his medicine, ask your doctor or pharmacist.

## . POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets very
Very common (may affect more than 1 in 0 people)
With normobaric treatment: In newborns damage to high oxygen concentrations Damage to the eye, which can result in
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 With hyperbaric treatment: Convulsions
Uncommon (may affect up to 1 in 100 people) Uncommon (may affect up to 1 in 100 people
With normobaric treatment: lung collapse
atelectasis). With hyperb
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 rom the available data)
With normobaric treatment: Pulmonary toxicity, aggravation of the excess carbon
dioxide in the blood (hypercapnia) mucosa dryness, local irritation and inflammation of dryness, local.
With hyperbaric treatment: breathing difficulty, involuntary muscular contraction, vertigo, 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. This includes any possible sid effects not listed in this leaflet. You can also
Scheme
(Website: www.mhra.gov.uk/yellowcard). By reporting side effects you can help
more information on the safety of this
more inform
medicine.
5. HOW TO STORE MEDICINAL OXYGEN Keep this medicine out of the sight and reach f children.
Do not use this medicine after the expiry date ed on the gas cylinder after EXP. The expiry date refers to the last day of that month
between -20 $0^{\circ} \mathrm{C}$ and should be stored
between $-20^{\circ} \mathrm{C}$ and $+65^{\circ} \mathrm{C}$.
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, fo placing them in a crate.

The gas cylinders should be stored in a or the storage room that is exclusively used forage rorage of medicinal gases. This 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

- 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 weath protected against the effects of the weather - 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 OTH

 INFORMATIONWhat medicinal oxygen contains

- The active substance is oxygen, $100 \% \mathrm{v} / \mathrm{v}$.

What medicinal oxygen looks like and

## What medicinal oxyg 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 pressure of 150,200 or 300 bars (at $15^{\circ} \mathrm{C}$ The cylinders are made of steel or aluminium. The valves are made of brass, steel or aluminium.
Marketing Authorisation Holder and
Manufacturer Manufacturer
Marketing Authorisation Holder
SOL S.p.A.
via Borgazzi 27 - 20900 Monza, Italy

## Manufacturer

B.T.G. Sprl
Zoning Quest 15, 7860 Lessines, Belgium Vivisol lbérica, S.L.
C/ Yeso 2, Polígono C/ Yest 2, Polígono Velasco
Arganda del Ray, 28500 Madrid, Spain sOL S.p.A.
ia Acquaviva 4, 26100 Cremona, Italy
12 VIadaiska Reva Str., 1510 Sofia, Bulgaria
SPG - SOL Pin Goreniska d.o.o
Cesta železariev 8 , 4270 Jesenice, Slovenia
SOL Technische Gaze GmbH
Marie-Curie Strasse 1, 2700 Wiener Neustadt
Austria Austria
Dolby Medical Home Respiratory Care Limited Unit 18, Arkwright Road Industrial Estate MK42 OLQ, United Kingdom
Dolby Medical Home Respiratory Care Limited Unit 2, Broadleys Road Springkerse Industrial Estate, Stirling
FK7 7ST, United Kingdom SOL Bulgaria EAD
SOL Bulgaria EAD 9160 Devnjia, Bulgaria
Sol France, sucursal España (SOLFSE) Call Telégraft, s/n, Nt.17-19,
Polígono Industrial So ta M Mol Polígono Industrial Sola el Molí,
08160 Montmeló, (Barcelona), Sp The Irish Company Oxygen ltd.
Waterfall Road, Cork, T12 PP40, Ireland

Czech Repubic : Kyslík medicinální plynný
 Hungary: Oxigén SOL
Luxembourg: Oxygène Médicinal Gazeux B.T.G Portugal: Oxygénio medicinal gasoso SOL Romania: Oxygen SOL
Slovakia: Medicinálny kyslik plynń SoL Slovenia: Medicinskki kisik SOL $100 \%$ medicinski pin, stisnjeni Spain: Oxigenom medicinal gas Solgroup
UK: Medical Oxygen UK: Medical Oxygen
This leaflet was last revised in 04/2024

## Member

Belgium: 0 )
Bulgaria: Медициннски кислород, газообразен SOL

| Packaging | Available sizes (1)* |
| :--- | :--- |
| * |  |

Aluminium cylinder with valve with integrated pressure regulation Steel cylinder with valve with integrated pressure regulation
, 2, $, 5,7,8,10,11,20,30,40,47,50$ Aluminium cylinder with traditional or step-down valve $1,2,3,5,5,7,8,10,11,20,30,40$, 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 $1,2,3,5,7,8,10,11,20,30,40,47,50$ Aluminium cylinder bundles with traditional or step-down valve $4 \times 50,8 \times 50,12 \times 50,16 \times 50,20 \times 50$ ${ }^{*} 71,401$ and 471 available for 150 bar filling pressure only.





SOL Hungary Kt. Dunaharas And as utca 6 AE - Te indos, Industrial zone Sindos 12th km Thessaloniki-Edessa, TAE - Technika Atria Ellados Thesis Stefani, Aspropyrgos Attiki Thesis isefana, Greece
This medicinal product is authorised in the Member States of the EEA under the following

Belgium: Oxygène Médicinal Gazeux B.T.G. $0,8 \times 50,12 \times 50,16 \times 50,20 \times 50$
7,40 and 47 l available for 150 bar filing pressure only.
reg
Use only with a suitable reducing
device
For 300 bar cylinders only
Use only with a suitable reducing

Gas cylinders with a content of $(x)$ litres contain $(y)$ kg of gas and deliver $(z) \mathrm{m}^{3}$ of oxygen at $15^{\circ} \mathrm{C}$ and 1 bar

Number of $\mathrm{m}^{3}$ of oxygen (z)
Not all cylinder sizes may be marketed.
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