

Medical Oxygen 100%

medicinal gas, compressed
Oxygen

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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

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.

Warning and precaution

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**
- **Ears, 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 to 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.

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) 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 medicinal oxygen exactly as your doctor has told you. You should 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



The following information is intended for medical or healthcare professionals only:

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.

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 product, 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 1,000 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. 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 medicinal oxygen after the expiry date which is stated on the gas cylinder after the abbreviation EXP.

- 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.

- 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 Medical Oxygen contains

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

What Medical 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.

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.

Gas cylinders with a content of (x) litres deliver (y) m ³ of oxygen at 15°C and 1 bar when filled to 200 bar .						
Content in litres (x)	1	2	5	10	20	30
Number of m ³ of oxygen (y)	0.212	0.425	1.125	2.12	4.33	6.37
Content in litres (x)	50	4 x 50	8 x 50	12 x 50	16 x 50	20 x 50
Number of m ³ of oxygen (y)	10.61	42.5	85.0	127.5	170.0	212.0

Gas cylinders with a content of (x) litres deliver (y) m ³ of oxygen at 15°C and 1 bar when filled to 300 bar .						
Content in litres (x)	1	2	5	10	20	30
Number of m ³ of oxygen (y)	0.308	0.616	1.54	3.08	6.16	9.24
Content in litres (x)	50	4 x 50	8 x 50	12 x 50	16 x 50	20 x 50
Number of m ³ of oxygen (y)	15.4	61.6	123	185	246	308

The shoulder of the cylinder is colour-coded in white. The colour of the cylinder body is white. The gas cylinders, valves and valve outlets conform to relevant EU standards. Not all cylinder sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Dolby Medical
Home Respiratory Care Limited
North Suite
Lomond Court, Castle Business Park
Stirling FK9 4TU, United Kingdom

Manufacturer

B.T.G. Sprl - Zoning Ouest 15, 7860 Lessines, Belgium
Dolby Medical, Home Respiratory Care Limited
Unit 18, Arkwright Road Industrial Estate
Arkwright Road, Bedford
MK42 0LQ, United Kingdom

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- 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.