

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Medical Oxygen 100% Medicinal gas, compressed Oxygen

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use medicinal oxygen carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve .
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What medicinal oxygen is and what it is used for
2. Before you use medicinal oxygen
3. How to use medicinal oxygen
4. Possible side effects
5. How to store medicinal oxygen
6. Further 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. 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.

### Take special care with medicinal oxygen

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.
- Do not under any circumstance change the concentration of the oxygen being supplied as to avoid fluctuations in oxygen saturation.

### 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**
- **fear 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.

### Using other medicines

Before using medicinal oxygen, talk to your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.**

#### **Using medicinal oxygen with food and drink**

**Do not drink any alcohol** during oxygen therapy. Alcohol can suppress breathing.

#### **Pregnancy and breast-feeding**

- 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.

Ask your doctor or pharmacist for advice before taking any 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 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 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 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 product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicinal products, medicinal oxygen can cause side effects, although not everybody gets them. The side effects have been grouped according to therapy.

**Oxygen therapy at normal pressure may result in:**

- a slight reduction in pulse
- heart failure
- shortness of breath
- chest pain
- fatigue
- inflammation of the tissue that lines the lungs and chest cavity (pleuritis)
- severe lung disease

In patients with breathing disorders whose breathing is triggered by a reduced oxygen level in the blood, the administration of oxygen may further reduce breathing effectiveness, and can result in an accumulation of carbon dioxide and excessive acid in the body (acidosis).

In new-born infants and pre-term new-born infants the administration of oxygen may result in eye damage, malformations of the lungs, bleeding in the heart, brain or spinal cord, and in inflammation and necrosis of intestines (necrotising enterocolitis). You should notify your doctor about even the smallest change in the baby's' medical condition.

**Oxygen therapy at high pressure may result in:**

- temporary loss of eyesight
- nausea
- dizziness
- anxiety and confusion
- muscle cramps
- loss of consciousness
- seizures (epileptic fits)
- damage to the middle ear caused by pressure fluctuations
- damage to the lungs due to pressure fluctuations
- pain, possibly accompanied by inflammation and bleeding in the paranasal sinuses caused by pressure fluctuations
- aching muscles

These undesirable effects may disappear in the course of time.

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

**5. HOW TO STORE MEDICINAL OXYGEN**

Keep out of the reach and sight 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. FURTHER 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, 230 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<sup>3</sup> of oxygen at 15°C and 1 bar when filled to 200 bar.

<i>Content in litres (x)</i>	<i>1</i>	<i>2</i>	<i>5</i>	<i>10</i>	<i>20</i>	<i>30</i>
Number of m <sup>3</sup> of oxygen (y)	0.212	0.425	1.125	2.12	4.33	6.37
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<i>Content in litres (x)</i>	<i>50</i>	<i>4x50</i>	<i>8x50</i>	<i>12x50</i>	<i>16x50</i>	<i>20x50</i>
Number of m <sup>3</sup> 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<sup>3</sup> of oxygen at 15°C and 1 bar when filled to 230 bar.

<i>Content in litres (x)</i>	<i>1</i>	<i>2</i>	<i>5</i>	<i>10</i>	<i>20</i>	<i>30</i>
Number of m <sup>3</sup> of oxygen (y)	0.240	0.480	1.200	2.400	4.800	7.200
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<i>Content in litres (x)</i>	<i>50</i>	<i>4x50</i>	<i>8x50</i>	<i>12x50</i>	<i>16x50</i>	<i>20x50</i>
Number of m <sup>3</sup> of oxygen (y)	12.00	48.00	96.00	144.0	192.0	240.0

Gas cylinders with a content of (x) litres deliver (y) m<sup>3</sup> of oxygen at 15°C and 1 bar when filled to 300 bar.

<i>Content in litres (x)</i>	<i>1</i>	<i>2</i>	<i>5</i>	<i>10</i>	<i>20</i>	<i>30</i>
Number of m <sup>3</sup> of oxygen (y)	0.308	0.616	1.54	3.08	6.16	9.24
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<i>Content in litres (x)</i>	<i>50</i>	<i>4x50</i>	<i>8x50</i>	<i>12x50</i>	<i>16x50</i>	<i>20x50</i>
Number of m <sup>3</sup> 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 Ltd  
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  
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Dolby Medical Home Respiratory Care Limited  
Unit 2, Springkerse Industrial Estate  
Broadleys Road  
Stirling  
FK7 7ST  
United Kingdom

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### **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.
- 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.