

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Medicinsk Oxygen "Air Liquide" 100%, Medicinal gas, cryogenic**

Oxygen 100% (O<sub>2</sub>)

Cryogenic means deep cold.

#### **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 Medicinsk Oxygen Air Liquide 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 effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **What is in this leaflet**

1. What Medicinsk Oxygen Air Liquide is and what it is used for –
2. Before you use Medicinsk Oxygen Air Liquide
3. How to use Medicinsk Oxygen Air Liquide
4. Possible side effects
5. How to store Medicinsk Oxygen Air Liquide
6. Further information

#### **1. What Medicinsk Oxygen Air Liquide is and what it is used for**

Medicinsk Oxygen Air Liquide contains oxygen, which is used for inhalation. It is colourless, odourless and tasteless, and is supplied in cryogenic vessels that have a dosing device to regulate the flow. The vessel contains only pure liquefied oxygen (cooled to approx. –180°C).

Medicinsk Oxygen Air Liquide increases the level of oxygen in the blood (increased oxygen saturation). Medicinsk Oxygen Air Liquide results in more oxygen being transported to all the tissues in the body.

Medicinsk Oxygen Air Liquide is used:

- To treat or prevent acute or chronic oxygen deficiency
- As a propellant for inhalation of other medicinal products (nebuliser treatment)
- As part of the gas flow in anaesthesia, pain relief and intensive care
- In pressurised chambers to reduce the risk of damage caused by decompression sickness, gas or air bubbles in blood vessels and in treatment of severe carbon monoxide poisoning and gangrene
- For treatment of an acute attack of cluster headache

#### **2. What you need to know before you use Medicinsk Oxygen Air Liquide**

##### **Do not use Medicinsk Oxygen Air Liquide**

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**

Talk to your doctor or pharmacist before using Medicinsk Oxygen Air Liquide

Before to start the 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 lung), 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.
- Adverse events such as eye damage may occur in new-born infants and pre-term new-born infants. If your baby requires extra oxygen, the doctor will determine the appropriate concentration of oxygen to be administered.

Hyperbaric oxygen therapy requires precautions in case of:

- **chronic obstructive pulmonary disease (COPD)**
- **lung emphysema**: a disorder of the lungs due to the loss of elasticity of lung tissue accompanied by (serious) shortness of breath
- **infections in the upper respiratory tract**
- insufficiently controlled **asthma**
- recent **middle ear surgery**
- recent **thoracic surgery**
- **uncontrolled high fever**
- **history of epilepsy or convulsions**
- **fear of confined spaces** (claustrophobia)
- 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**

**Advice regarding the increased risk of fire in presence of 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 Medicinsk Oxygen Air Liquide is used, as it increases the risk of fire.
- Do not smoke nor use e-cigarette all along your treatment with oxygen.
- Do not use toasters, hairdryers, or similar electrical equipment during your treatment with oxygen.
- Do not apply greasy substances (e.g. oils, creams, ointments) on surfaces in contact with oxygen. Only water-based products should be used on the hands and face or inside the nose while using oxygen.
- The pressure regulator must be opened slowly and cautiously to avoid the risk of flash fire.

Thermal burns have occurred related to accidental fire in presence of oxygen.

**Advice to caretakers:**

- Handle carefully the cylinder. Ensure that the gas cylinder is not dropped or exposed to knocks.
- Equipment damage may cause obstruction of the outlet and/or wrong information displayed on the manometer with regards to remaining oxygen content and flow delivery leading to insufficient or lack of oxygen administration.
- Oxygen becomes a fluid at approximately  $-183^{\circ}\text{C}$ . There is a risk of burns at such low temperatures. Always wear gloves and protective goggles when working with medicinal liquid oxygen.

**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.

**Other medicines and Medicinsk Oxygen Air Liquide**

Tell your doctor or pharmacist if you are taking or have recently taken 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.

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

Medicinsk Oxygen Air Liquide can be used during pregnancy but when it is needed only.

Medicinsk Oxygen Air Liquide can be used during the period of breast-feeding.

In all situations, you should inform your doctor if you are pregnant or suspect you might be pregnant.

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**

You may drive and use machines when using Medicinsk Oxygen Air Liquide provided your doctor considers that you are both fit and capable.

## **3. How to use Medicinsk Oxygen Air Liquide**

Always use Medicinsk Oxygen Air Liquide exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults to treat or prevent *acute oxygen deficiency* is 3–4 litres per minute when using nasal prongs, or 5–15 litres per minute with a mask. For the dosage in other cases consult your doctor.

Medicinsk Oxygen Air Liquide is usually breathed through nasal prongs or a mask. Either you breathe yourself – you “breathe spontaneously” – or you are helped to breathe by means of a respirator/ventilator.

### **If you use more Medicinsk Oxygen Air Liquide than you should**

In vulnerable situations, excessive administration of Medicinsk Oxygen Air Liquide can affect respiratory function and in exceptional cases cause neurological adverse effects which can lead to a loss of consciousness in extreme situations.

Prolonged use of too much Medicinsk Oxygen Air Liquide can cause a breathing-related pain, a dry cough, and even breathlessness. If these signs of overdose occur, always contact your doctor or the nearest hospital.

### **Safety instructions**

- Medicinsk Oxygen Air Liquide is intended for medical use only.
- Oxygen must only be used in rooms with good ventilation.
- Keep the vessels upright. If the vessels fall over, liquefied Medicinsk Oxygen Air Liquide may leak and cause severe cold damage. With normal use the cold liquefied oxygen does not cause any damage. If oxygen escapes from the vessel it is converted to oxygen in its usual gaseous form.
- The vessels should not be exposed to strong heat.
- There must be no smoking or open flames in rooms where Medicinsk Oxygen Air Liquide is used, as it increases the risk of fire.
- Do not use toasters, hairdryers or similar electrical equipment during treatment with Medicinsk Oxygen Air Liquide.
- Never place an oxygen mask or nasal prongs directly on textiles while treatment is being carried out – fabrics that become saturated with oxygen can be highly flammable/cause a risk of fire. If this should occur, thoroughly shake and air the textiles.
- Never use grease, oil or similar substances for lubricating screw threads that jam since there is a risk of self-combustion in contact with Medicinsk Oxygen Air Liquide.
- Switch off the equipment when it is not in use.

- In the event of fire – switch off the equipment.
- Vessels must be carried to safety in the event of a danger of fire.
- Handle carefully. Ensure that the vessel is not being dropped or exposed to knocks.
- Keep the vessel clean and dry.
- Must be stored and transported with the valve closed

#### 4. Possible side effects

Like all medicines, Medicinsk Oxygen Air Liquide can cause side effects, although not everybody gets them.

Side effects are usually seen with high concentrations and after prolonged treatment:

##### **Very common (may affect more than 1 in 10 people):**

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: convulsion.

##### **Uncommon (may affect up to 1 in 100 people):** lung collapse,

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.

**Undetermined frequency (frequency cannot be estimated from the available data):** breathing-related pain and dry cough, mucosal dryness, local irritation and inflammation of the mucosa.

With hyperbaric treatment: breathing difficulty, involuntary muscular contraction, vertigo, audition impairment, acute serous otitis, sickness, abnormal behaviour, decrease in peripheral vision, visual changes, clouding of the lens (cataract).

Contact with liquid oxygen causes frostitis.

##### **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 the national reporting system listed in [Appendix V\\*](#). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Medicinsk Oxygen Air Liquide

Keep out of the reach and sight of children.

Do not use Medicinsk Oxygen Air Liquide after the expiry date that is stated on the batch label.

Keep the vessels in a well-ventilated place where it is not exposed to strong heat.

Keep the vessel clean and dry.

Ensure that the vessel is not dropped or exposed to knocks.

Store away from combustible materials.

## **6. Contents of the pack and other information**

### **What Medicinsk Oxygen Air Liquide contains**

- The active substance is 100% oxygen (chemical symbol: O<sub>2</sub>)
- There are no other components in Medicinsk Oxygen Air Liquide

### **What Medicinsk Oxygen Air Liquide looks like and contents of the pack**

Packs:

Cryogenic vessels, mobile: 180, 228, 450, 500, 600, 627, 800 litres (only supplied to the clinic)

Cryogenic vessels fitted with a dosing device for regulation of the flow to the patient.

Sizes: 0.5, 1.2, 10, 12, 15, 20, 21, 30, 31, 32, 36, 37, 40, 44 litres.

Cryogenic vessels, fixed: 800 – 64000 litres.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

AIR LIQUIDE Santé INTERNATIONAL

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### **Manufacturers**

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