

Linde Medicinal Oxygen 100%v/v

Medicinal Oxygen (100%v/v)

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WHAT LINDE MEDICINAL OXYGEN IS USED FOR

Linde Medicinal Oxygen can be used under normal pressure or in pressure chambers (so called hyperbaric treatment).

Under normal pressure Linde Medicinal Oxygen is used:

- for the treatment of acute or chronic hypoxia (low oxygen levels in the blood).
- as part of the gas flow used during general anaesthesia (narcosis) and intensive care.
- for driving a nebuliser during inhalation of inhaled medications.
- as first aid treatment with 100% oxygen in association with diving accidents.
- for treatment of acute attacks of cluster headache among adults only.

Under high pressure Linde Medicinal Oxygen can be used in pressure chambers to:

- increase the oxygen content of the blood and the tissues to reduce the risk of damage caused by decompression sickness, gas or air bubbles in blood vessels.
- treat carbon monoxide poisoning

- treat tissue infections (clostridial myonecrosis, gas gangrene)

HOW LINDE MEDICINAL OXYGEN WORKS

Linde Medicinal Oxygen increases the level of oxygen in the blood (increases oxygen saturation) resulting in more oxygen being transported to all the tissues in the body.

BEFORE YOU USE LINDE MEDICINAL OXYGEN

Linde Medicinal Oxygen is prescribed to you by a doctor. Ensure that your doctor is aware of any medical conditions that you may have.

When you must not take it

Linde Medicinal Oxygen should not be used in pressure chambers if you have:

- an untreated damage of the pleura, a so-called pneumothorax.
- had surgery or trauma to the body since this event can cause gas bubbles in the body.

Linde Medicinal Oxygen should not be used for treatment of an acute attack of cluster headache in children or adolescents.

Before you start to use it

Inform your doctor if you suffer from chronic lung disease for example asthma or chronic obstructive pulmonary disease (COPD).

Newborns, especially premature babies, are more vulnerable to oxygen than adults.

Only give the amount of Linde Medicinal Oxygen advised by your healthcare professional.

Linde Medicinal Oxygen treatment under normal pressure

Linde Medicinal Oxygen can be used

during pregnancy and during the period of breast-feeding. Treatment with Linde Medicinal Oxygen has no known negative effect on fertility.

Linde Medicinal Oxygen treatment under high pressure

If you are prescribed treatment with Linde Medicinal Oxygen in a pressure chamber,

- the risk associated to damage of the pleura (so called pneumothorax) should be acknowledged.
- you should inform your doctor if you are pregnant or suspect you might be pregnant since there is a potential risk of so called oxidative stress damage in the baby.
- breast-feeding should be avoided during the actual treatment since there is a risk for the newborn child to be exposed to the pressure and compression in the pressure chamber. Breast-feeding can be safely done prior to or after treatment in the pressure chamber. There are no known side effects of treatment on breast-feeding when Linde Medicinal Oxygen is used in a pressure chamber.

The effects on fertility when Linde Medicinal Oxygen is used in a pressure chamber have not been studied.

Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking or have been prescribed: bleomycine, cisplatin, or doxorubicin (medicine to treat cancer), amiodarone (medicine to treat heart disease), furadantin (nitrofurantoin) or similar antibiotics (medicine to treat infections), disulfiram (medicine to treat alcohol abuse) and chemicals such as paraquat, please advise your doctor before using this medicine, as there is a possibility that the treatment may increase the risk for lung damage.

HOW TO USE LINDE MEDICINAL OXYGEN

If you are using this medicine at home, ensure you are trained on the use of Linde Medicinal Oxygen and the equipment when you receive your first supply.

How much to use

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure. Do not alter the dosage without first consulting your doctor.

Read the instructions for use/patient instructions for your breathing equipment carefully!

- The recommended dose is decided for you individually based on your medical condition. The usual dose for adults to treat or prevent acute oxygen deficiency under normal pressure is 2-6 litres per minute when using nasal prongs, or 5–10 litres per minute with a face mask and 10-15 litres per minute with a reservoir mask.
- For the dosage in other cases consult your doctor.

Children of any age can be treated with Linde Medicinal Oxygen treatment under normal pressure, but specific care should be taken in newborns.

When to use it

- Linde Medicinal Oxygen is intended for medical use only. Only connect the cylinder to a connection intended for medicinal oxygen.
- Linde Medicinal Oxygen is used by inhalation. It is usually breathed through nasal cannula or face mask, which is connected to your oxygen system with a tubing provided.
- Either you breathe yourself (you “breathe spontaneously”) or you are helped to breathe by means of a respirator/ventilator.

When using Linde Medicinal Oxygen, you must:

- ensure that the cylinder is stood upright on a flat surface and supported so that it will not fall over. Small cylinders may be laid down if appropriate. Never place the cylinder on your bed when it is in use.

- check the contents gauge (pressure gauge) on the cylinder or the pressure regulator before you start to make sure there is enough gas available for your use.
- check that the tubing is correctly fitted to the outlet.
- select the flow prescribed by your healthcare professional, as advised by your homecare provider.
- ensure that all your cylinder and any additional delivery equipment is kept free from oil and grease.
- handle valves and devices connecting to the Linde Medicinal Oxygen with clean and grease-free (hand cream etc) hands.
- open the cylinder valve slowly and carefully to avoid ignition.

How long to use it

Linde Medicinal Oxygen treatment under normal pressure

Follow your healthcare provider's instructions. Some people need it temporarily until they recover from an acute (short-term) illness, while others with chronic conditions need supplemental oxygen for longer term.

Linde Medicinal Oxygen treatment under high pressure

The length of treatment and how often you should receive Linde Medicinal Oxygen is decided by the doctor.

If you forget to use it

It is important to take your medicine every day as a regular treatment works better.

If you forget to take, take as soon as you remember, and continue to take it as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you use too much (overdose):

You might get signs of overdose if you use more Linde Medicinal Oxygen than you should. Too much of this medicine can:

- cause pain, a dry cough, and breathlessness
- affect respiratory function and in exceptional cases (for instance in some patients that suffer from

chronic lung disease) can cause reduced breathing and loss of consciousness.

If these signs of overdose of Linde Medicinal Oxygen occur, always contact your doctor. If you experience severe symptoms seek medical attention immediately.

If you have any further questions on the use of this medicine, ask your doctor.

WHILE YOU ARE USING IT

Things you must do

- Always use Linde Medicinal Oxygen exactly as your homecare provider has shown you. You should check with your homecare provider if you are not sure.
- Oxygen (container and cylinder) must only be used in rooms with good ventilation.
- Turn the cylinder valve ‘OFF’ with moderate force only when the cylinder is not in use.
- Close the valve when the cylinder is empty using moderate force only.
- In the event of fire, switch off the equipment and carry the gas cylinders to safe place.
- If a leak occurs, this will be evident by a hissing noise. Close the cylinder valve and check the connection of the tubing to the outlet. If the leak continues close the valve and contact your homecare provider.

Things you must not do

- There must be NO SMOKING or open flames in rooms where Linde Medicinal Oxygen is used, as it increases the risk of fire.
- 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 and has a risk of fire. If this should occur, thoroughly shake and air the textiles.
- NEVER use oil based moisturising creams with your cylinder equipment.
- If using alcohol gels allow plenty of time for the alcohol gel to dry before handling oxygen equipment.

- Never use grease, oil or similar substances for lubricating screw threads that jam. There is a risk of self-combustion in contact with Linde Medicinal Oxygen under high pressure.
- Do not use toasters, hairdryers, or similar electrical equipment during treatment with Linde Medicinal Oxygen.
- Do not use this medicine if you notice the cylinder does not have an intact tamper evident seal when delivered to you.
- Do not use Linde Medicinal Oxygen after the expiry date which is stated on the label as "Exp".

Things to be careful of

Take special care when using Linde Medicinal Oxygen if:

- your baby requires extra oxygen and is premature. Only give the amount of Linde Medicinal Oxygen advised by your healthcare professional
- you are suffering from chronic lung disease, such as bronchitis or emphysema. The amount of Linde Medicinal Oxygen used must be carefully controlled to the flow rate that has been prescribed to you by your healthcare professional.

Driving and using machines

You may drive after using Linde Medicinal Oxygen providing that your doctor considers that you are both fit and capable of driving.

SIDE EFFECTS

Like all medicines, Linde Medicinal Oxygen can cause side effects, although not everybody gets them.

Side effects are usually seen with high concentrations (over 70%) and after prolonged treatment (at least 6–12 hours).

Linde Medicinal Oxygen treatment under normal pressure

The most serious side effect that may occur is severe difficulty breathing, so called respiratory distress syndrome (that may lead to pulmonary fibrosis). If you experience difficulties breathing stop taking the medicine and/or seek urgent medical advice.

Uncommon (may affect up to 1 in 100

people)

- Dry mucous membranes in the nose and mouth on account of the gas being dry. Breathing-related pain and dry cough and breathlessness

Rare (may affect up to 1 in 1000 people)

- In newborns exposed to high oxygen concentrations: Damage to the eye, which can result in impaired vision.
- Respiratory depression (reduced breathing)

Very rare (may affect up to 1 in 10,000 people)

- Severe difficulty breathing (respiratory distress syndrome)

Burns

- If you get any of these side effects stop the treatment and talk to your doctor.

Linde Medicinal Oxygen treatment under high pressure

The most serious side effects are confusion and convulsions (epilepsy). Healthcare professionals are always present when you are treated with Linde Medicinal Oxygen under high pressure. Your doctor will take action if you should experience any of these side effects.

Uncommon (may affect up to 1 in 100 people)

- Feeling pressure in the middle ear, rupture of the eardrum

Rare (may affect up to 1 in 1000 people)

- Sensation of pressure/pain in the nose

Very rare (may affect up to 1 in 10,000 people)

- Anxiety, impaired vision, barotrauma (damage to tissues because of the pressure effect), confusion, loss of consciousness, and convulsions (epilepsy).

Linde Medicinal Oxygen treatment under normal pressure among children

Special caution should be taken when newborns are treated, since they are more vulnerable to some side effects than other patients.

The most serious side effect in newborns is damage to the eye (retrolental fibroplasia) that can cause

impaired vision and lung dysfunction so called broncho-pulmonary dysplasia.

If you suspect that your child has got any of these side effects stop the treatment and talk to your doctor immediately.

Except for the most serious side effects just described, there are no other known side effects in children than those that has been reported in adults.

Linde Medicinal Oxygen treatment under high pressure

There are no known additional side effects caused by treatment with Linde Medicinal Oxygen in a hyperbaric chamber than those that have been reported in adults.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via channels stated in the NPRA's ADR (Adverse Drug Reactions) reporting website: <https://www.npra.gov.my/index.php/en/health-professionals/reporting-adr.html>. By reporting side effects, you can help provide more information on the safety of this medicine.

STORAGE AND DISPOSAL OF LINDE MEDICINAL OXYGEN

Storage

- Keep this medicine out of the sight and reach of children.
- Keep the cylinder in a well-ventilated place where it is not exposed to strong heat.
- Keep the cylinder clean and dry.
- Ensure that the gas cylinder is not dropped or exposed to knocks.
- Store away from combustible materials.
- Cylinders must be stored and transported with the valve closed and, where used, with the protective cap and cover in place.

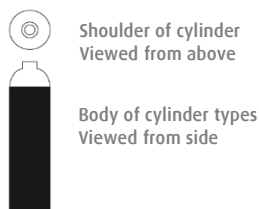
Disposal

- The cylinders must be returned to the supplier after using.

PRODUCT DESCRIPTION**SERIAL NUMBER****What it looks like**

NPRA (R2) 23/220

Linde Medicinal Oxygen is colourless, odourless and tasteless gas, supplied in gas cylinders. The gas cylinder contains only pure oxygen. The colour of Linde Medicinal Oxygen cylinder is black body with white shoulder.



Shoulder of cylinder
Viewed from above

Body of cylinder types
Viewed from side

Ingredients**Active ingredient(s):**

Medicinal oxygen 100%v/v

Inactive ingredients:

There are no excipients.

MAL number:

MAL24016033X

MANUFACTURER**Linde EOX Sdn Bhd (451806-K)**

Lot 36, Section 66, Jalan Peteri,
Bintawa Industrial Estate,
93460 Kuching,
Sarawak.

**PRODUCT REGISTRATION
HOLDER****Linde Malaysia Sdn Bhd (100783-W)**

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Persiaran Lagoon,
Bandar Sunway
47500 Petaling Jaya,
Selangor Darul Ehsan.

DATE OF REVISION

24 Jan 2024