

LEEDEN MEDICINAL OXYGEN 100% V/V

(Medicinal Oxygen, 100% v/v)

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1. What Leeden Medicinal Oxygen is used for?

Leeden Medicinal Oxygen can be used for normobaric treatment (under normal pressure) or hyperbaric treatment (in pressure chambers).

Leeden Medicinal Oxygen under normal pressure is used:

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

Medical Oxygen under high pressure 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 tissue infections (clostridial myonecrosis, gas gangrene).
- Treat carbon monoxide poisoning

2. How Leeden Medicinal Oxygen works

Leeden Medicinal Oxygen is being inhaled into body and uptake by blood and send to other parts of body.

3. Before you use Leeden Medicinal Oxygen

- Make sure your doctor is informed of any potential medical conditions you may have.
- Do not smoke or allow anyone near you to smoke during treatment with Leeden Medicinal Oxygen as it can cause fires.
- Hyperbaric oxygen therapy should not be used if you have a collapsed lung that has not been treated or drained.

Warnings and Precautions

Talk to your doctor before using the Leeden Medicinal Oxygen.

You should know the following before starting the oxygen therapy:

- High amounts of oxygen might be hazardous. This could result in lung injury (lung inflammation, collapse of the alveoli), which would stop the blood's flow of oxygen.
- The oxygen flow rate will be low if you have severe chronic obstructive pulmonary disease (COPD), which leads to a deficiency in blood oxygenation.
- Unfavourable outcomes, like eye impairment, can happen to newborn babies.

Note:

Please consult your doctor for the appropriate amount of Leeden Medicinal Oxygen to be given.

Pregnancy and Lactation

- At normal pressure, Leeden Medicinal Oxygen can be used during pregnancy and breast-feeding.
- Hyperbaric oxygen therapy should be used with caution as there is potential risk on the foetus from oxidative stress from excess oxygen.

Taking Other Medicines

If you are taking bleomycin, nitrofurantoin, amiodarone and with paraquat intoxication, you must tell your doctor before using this product.

4. How to take Leeden Medicinal Oxygen

Dosage

Please consult your doctor for recommended dosage as every individual have different medical condition.

- The usual dose for adults to prevent or treat acute oxygen deficiency under normal pressure is 2-6 litres per minute with a reservoir mask.
- For the dosage in other cases consult your doctor.

Under normal pressure, children of any age can be administered Leeden Medicinal Oxygen treatment; however special attention is required for newborns.

Instruction of Use

1. Use the dedicated equipment such as face mask to administer the Leeden Medicinal Oxygen.

2. Medical gases must only be used for medicinal purposes only.

3. Cylinders should be handled with care and not knocked violently or allowed to fall.

4. When in use cylinders should be firmly secured to a suitable cylinder's support.

5. Remove the cylinder seal cap from valve before use.

6. Cylinder valves should be opened momentarily prior to use to blow any foreign matter out of the outlet.

7. Ensure you are using the correct regulator for the specific gas and that there is sufficient gas in the cylinder by checking the contents gauge before starting.

8. Check that the tubing is correctly fitted to the outlet.

9. Select the flow prescribed by your doctor.

10. Cylinder valves must be opened slowly.

Symptoms and Treatment of Overdose

The symptoms of oxygen intoxication are those of pain, dry cough, and breathlessness, and the treatment is by reducing the oxygen therapy or stopped (if possible). Symptomatic treatment should be done.

Always call your doctor if you experienced any of the symptoms of a Leeden Medicinal Oxygen overdose. If your symptoms become severe, immediately seek medical attention.

Consult your doctor if you have any more questions regarding the usage of this product.

5. While you using it

Things you must do

- When only a small amount of gas remains in a cylinder, the cylinder valve must be closed. It is important to leave a small residual pressure in each cylinder after use, in order to protect the inside of the cylinder from contamination.

• After use cylinder valves should be closed using moderate force only and the pressure in the regulator or tailpipe released.

• If a leak occurs, it will usually be evident by a hissing noise. Please close the valve, check the connections from the tube to the outlet. If persist, close the valve and contact the product provider.

Things you must not do

• Refrain from smoking and do not allow naked lights within the vicinity of cylinders or pipeline outlets.

• Never lubricate cylinders, valves, or any associated equipment. Keep them free from oil and grease.

• Avoid using excessive force when connecting equipment to cylinders.

• Do not attempt to correct any leakage problems with the valve itself. Label any faulty containers and return them to the supplier for repair.

• Never use sealing or jointing compounds to cure a leak.

Things to be careful of

Leeden Medicinal Oxygen should be used with extra caution if:

• your baby is premature and needs more oxygen. Do not give more Leeden Medicinal Oxygen than your doctor has prescribed.

• you have a chronic lung condition like emphysema or bronchitis. You must carefully regulate the amount of Leeden Medicinal Oxygen you use in accordance with the flow rate that your healthcare provider has advised.

Driving and Using Machines

Under normal conditions, oxygen does not interfere with consciousness, however if the patients require continuous oxygen support will require individual assessment.

6. Side Effects

Below are the Adverse reactions associated with Normobaric Oxygen Therapy (NBOT) and Hyperbaric Oxygen Therapy (HBOT):

Very Common (>1/10)

NBOT: Retinopathy of prematurity

HBOT: Ear pain, Barotrauma and Progressive Myopia

Common (≥1/100 to <1/10)

HBOT: Ear pain

Uncommon (≥1/10,000 to (1/100)

HBOT: Tympanic membrane rupture

Rare (≥10,000 to 1/1,000)

HBOT: Dyspnoea and hypoglycemia in diabetic patients.

Very rare (≤1/10,000)

N/A

Likelihood of the Adverse Reactions that Cannot be Estimated from the Available Data

NBOT:

• Pulmonary toxicity (interstitial oedema, pulmonary fibrosis)

• Worsening of hypercapnia treated with too much elevated FiO₂ (hypoventilation, respiratory acidosis, respiratory arrest)

• Mucosal dryness

• Local irritation and inflammation of the mucosa

HBOT:

• Respiratory disturbances

• Localised muscular twitching

• Vertigo, Hearing impaired, Acute serous otitis media, Tinnitus

• Nausea

• Abnormal behaviour

• Peripheral vision decreased and blurred vision cataract

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of Leeden Medicinal Oxygen

Storage

• Kept away from sunlight, dry and clean place.

• Kept away from any flammable materials.

• Store in a well-ventilated place.

• Kept cylinder in upright position and secure it.

• Store at temperature below 50°C.

Disposal

Used cylinders should be returned to supplier immediately.

8. Product description

What it looks like

Leeden Medicinal Oxygen (gaseous) is a colourless, odourless gas supplied in a pressurised gas cylinder with a valve. The gas cylinder contains only Medical Oxygen. The gas cylinder's colour is black body with a white shoulder. Cylinder sizes between 3.4 to 50 L with content between 0.5 to 9.6 m³ at pressure between 150 to 200 bars.

Active ingredient(s):

Oxygen 100% v/v.

Excipient(s):

There are no excipients.

9. Manufacturer and Product Registration Holder

Leeden Gases Sdn Bhd.

Lot PT 5074 & 5075, Jalan Jangur 28/43, Seksyen 28, 40400 Shah Alam, Selangor Darul Ehsan, Malaysia

10. Date of Revision

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