

CONOXIA® Compressed Medicinal Oxygen 100% v/v with LIV®

Medicinal Oxygen 100% v/v

What is in the leaflet?

1. What CONOXIA is used for
2. How CONOXIA works
3. Before you use CONOXIA
4. How to use CONOXIA
5. While you are using CONOXIA
6. Side effects
7. Storage and Disposal of CONOXIA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial number

WHAT CONOXIA IS USED FOR

CONOXIA is cylinder equipped with LIV (Linde Integrated Valve) containing medicinal oxygen.

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

Under normal pressure CONOXIA 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 CONOXIA 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 CONOXIA WORKS

CONOXIA cylinder is equipped with LIV®, which is an integrated, portable, gas delivery system. The pressure regulator integrated in the cylinder valve is designed for use with medical gas cylinders to reduce the pressure to a significantly lower pressure, suitable for connecting medical devices (via quick connector) and for the direct administration of breathable gases to patients (via flow connector).

CONOXIA 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 CONOXIA

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

Before using CONOXIA, you must read the instructions and understand how to handle it safely.

When you must not take CONOXIA

CONOXIA 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.

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

Before you start to use CONOXIA

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 CONOXIA advised by your healthcare professional.

CONOXIA treatment under normal pressure

CONOXIA can be used during pregnancy and during the period of breast-feeding. Treatment with CONOXIA has no known negative effect on fertility.

CONOXIA treatment under high pressure

If you are prescribed treatment with CONOXIA 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 CONOXIA is used in a pressure chamber.

The effects on fertility when CONOXIA 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 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 CONOXIA treatment under normal pressure, but specific care should be taken in newborns.

When to use CONOXIA

- CONOXIA is intended for medical use only. Only connect the cylinder to a connection intended for medicinal oxygen.
- CONOXIA 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 CONOXIA, 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 CONOXIA with clean and grease-free (hand cream etc) hands.
- open the cylinder valve slowly and carefully to avoid ignition.

How long to use CONOXIA

CONOXIA 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.

CONOXIA treatment under high pressure

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

If you forget to use CONOXIA

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 CONOXIA 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 CONOXIA 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 CONOXIA

Things you must do

- Always use CONOXIA 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.
- In the event of leakage or defective cylinder package, close the valve, mark as "defective", put aside, and contact your homecare provider.
- Prepare to change the cylinder when the pointer on the gauge enters the red area.
- To ensure the correct, prescribed flow rate, always make sure that the flow selector is positioned on a numbered flow setting, not between flow settings.

Things you must not do

- There must be NO SMOKING or open flames or sparks in rooms where CONOXIA is used, as it increases the risk of fire.
- Do not use outside operating temperature range -20 °c to +45 °c
- 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 CONOXIA under *high pressure*.
- Do not use toasters, hairdryers, or similar electrical equipment during treatment with CONOXIA.
- 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 CONOXIA after the expiry date which is stated on the label as “Exp”.
- Do not attempt to disassemble the CONOXIA package.
- Do not attempt to refill the CONOXIA cylinder.
- Do not alter the markings or labels on the CONOXIA package.
- If the outside surface of the package must be cleaned, use only a soft cloth. The cloth may be dry or damp (with clean water). Do not use any cleaning solutions containing alcohol, aldehyde, ammonia or peroxide compounds.
- Do not immerse the product in water or any other liquids.
- Do not pour any liquids into the user outlets.

Things to be careful of

Take special care when using CONOXIA if:

- your baby requires extra oxygen and is premature. Only give the amount of CONOXIA advised by your healthcare professional.
- you are suffering from chronic lung disease, such as bronchitis or emphysema. The amount of CONOXIA 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 CONOXIA providing that your doctor considers that you are both fit and capable of driving.

SIDE EFFECTS

Like all medicines, CONOXIA 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).

CONOXIA 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.

CONOXIA treatment under high pressure

The most serious side effects are confusion and convulsions (epilepsy). Healthcare professionals are always present when you are treated with CONOXIA 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).

CONOXIA 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.

CONOXIA treatment under high pressure

There are no known additional side effects caused by treatment with CONOXIA 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 CONOXIA**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.
- Do not expose to temperature higher than + 65 °c. If at risk of fire, move to a safe place.
- Keep the cylinder package clean, dry and free from oil and grease.
- Ensure that the cylinder package cannot fall, is not dropped or exposed to knocks.
- Store away from combustible materials. Contact with combustible material can cause fire.
- Cylinders must be stored and transported with the valve closed and, with the protective cap and cover in place in a secured position.
- Do not stack LIV packages on top of each other as this can cause damage to the valve or the handling device.
- Do not expose to corrosive substances e.g. ammonia.

- If at risk of fire, move to a safe place.
- Keep the cylinder in storage reserved for medicinal gases.

Disposal

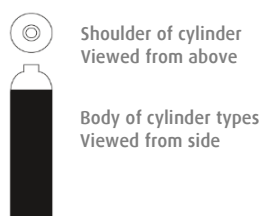
- The cylinders must be returned to the supplier after using.

PRODUCT DESCRIPTION**What CONOXIA looks like**

CONOXIA cylinder package consists of LIV and an aluminium gas cylinder.

LIV is an integrated valve consists of a pressure regulator, a flow outlet, a pressure outlet, and a bed hanger.

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



The above components are permanently fitted to the gas cylinder and must not under any circumstances be removed by the user.

The whole package is maintained by Linde Malaysia Sdn Bhd as the owner of this product.

Ingredients**Active ingredient(s)**

Medicinal oxygen 100%v/v

Inactive ingredients

There are no excipients.

MAL number

MAL24106004X

MANUFACTURER**Linde Gas Products Malaysia Sdn Bhd (453560-K)**

No. 1, Jalan Graphite 3,
Kawasan Perindustrian Bandar
Mahkota Banting,
42700 Banting, Kuala Langat,
Selangor Darul Ehsan.

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

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

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