

Package leaflet: Information for the user

Livopan 50%/50 % medicinal gas, compressed

Nitrous oxide / Oxygen

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Livopan is and what it is used for
2. What you need to know before you use Livopan
3. How to use Livopan
4. Possible side effects
5. How to store Livopan
6. Content of the pack and other information

1. What Livopan is and what it is used for

Livopan contains a ready mixture of nitrous oxide (medicinal “laughing gas”, N₂O) and oxygen (medicinal oxygen, O₂), 50% of each, and should be used by breathing in the gas mixture.

The effects of Livopan

The nitrous oxide constitutes 50% of the gas mixture. Nitrous oxide has a painkilling effect, reduces the sensation of pain, and raises the pain threshold. Nitrous oxide also has a relaxing and slightly calming effect. These effects are produced by the effects of nitrous oxide on signal substances in your nervous system.

The 50-percent concentration of oxygen, around double that in ambient air, guarantees a safe oxygen content in the inspired gas.

What Livopan is used for

Livopan should be used when painkilling effects, of rapid onset and rapid resolution are desired and when the treated pain state is of mild to moderate intensity and of limited duration. Livopan produces painkilling effects after just a few breaths and the painkilling effects subside within minutes after use is ceased. Livopan can be used in adults and children from 1 month old.

2. What you need to know before you use Livopan

Do not use Livopan:

Before you use Livopan you should inform your doctor if you have any of the following signs/symptoms:

- **Gas-filled cavities or gas bubbles:** if as a result of illness, or for any other reason it may be suspected that there is air in your pleural cavities outside the lungs, or gas bubbles in your blood or any other organ. E.g. if you have dived with diving equipment and may have gas bubbles in your blood, or if you have been treated with an injection of gas into the eye, e.g. for a retinal detachment or similar. These gas bubbles may expand and thereby cause harm.
- **Heart disease:** if you have heart failure or severely impaired heart function, since the slightly relaxing effect of nitrous oxide on the heart muscle can further impair cardiac function.
- **Central nervous system injury:** If you have increased pressure in the brain, e.g. resulting from a brain tumour or bleed in the brain, since nitrous oxide can further increase the pressure in the brain with potential risk of harm.
- **Vitamin deficiency:** If you have *diagnosed but untreated* vitamin B₁₂ deficiency or folic acid deficiency, since use of nitrous oxide can worsen the symptoms caused by vitamin B₁₂ and folic acid deficiency.
- **Ileus** If you have severe abdominal discomfort: symptoms which may indicate ileus, then Livopan may further increase the dilation of the gut.
- **Injuries to the face and jaw,** where use of a facemask may present difficulties or risks.

Warnings and precautions:

Also inform your doctor if you have any of the following signs/symptoms:

- **Decreased level of consciousness or persistent sign of confusion:** Inform your doctor if you feel unwell or feel that you due to trauma or disease are not fully awake. This is important because of the sedating effects, of the nitrous oxide component of Livopan, there is a risk of further sedation that may affect your natural protective reflexes.
- **Ear discomfort:** e.g. ear inflammation, since Livopan may increase the pressure in the middle ear.
- **Chronic Obstructive Pulmonary Disease (COPD),** since use of oxygen can cause respiratory depression.
- **Have or have had drug/medication abuse** because there is a higher risk of developing dependence to nitrous oxide if you take it repeatedly. Your doctor will decide whether treatment with Livopan is possible in your case.
- **Vitamin deficiency:** If you are *suspected* of having vitamin B₁₂ deficiency or folic acid deficiency, since use of nitrous oxide can worsen the symptoms caused by vitamin B₁₂ and folic acid deficiency.

Your doctor will decide whether Livopan is suitable for use.

Repeated or long-term use of nitrous oxide may increase the risk of vitamin B12 deficiency which may lead to damage of the bone marrow or the nervous system. Your doctor may initiate blood tests before and after the treatment in order to assess the consequences of the possible vitamin B12 deficiency.

Other medicines and Livopan

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

- Methotrexate for treating e.g. arthritis. Taking Livopan with methotrexate may have an effect on your blood cell count

Other medicines which affect the brain or brain function, e.g. benzodiazepines (tranquillising) or morphine like medicines, you should inform your doctor of this. Livopan can increase the effects of these medicines. Livopan in combination with other medicines affecting the central nervous system, increases the risk of side effects.

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- Bleomycin (to treat cancer) or amiodarone (to treat an irregular heartbeat) before using Livopan, as there is a possibility of toxic effects to the lungs due to the high concentration of oxygen.
- Nitrofurantoin or similar antibiotics (to treat infection)

Livopan increases the side effects of these medicines.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before this medicine is given to you.

Livopan may be used during pregnancy if the doctor considers it clinically needed. It may also be used during childbirth. If used close to delivery your baby should be observed for breathing difficulties (respiratory depression) and other adverse effects.

Livopan can be used during the breast-feeding period, but should not be used during breast-feeding itself.

Driving and using machines

You should be aware of that after having received Livopan you need to recover. The nitrous oxide component of Livopan vanishes rapidly from the body after brief inhalation. The effects on the cognitive capabilities can last for several hours. For safety reasons, you should avoid driving, using machines or carrying out complicated tasks until you are fully recovered (at least 30 minutes).

Ensure that your healthcare professional advises you whether it is safe for you to drive.

3. How to use Livopan

Livopan is always administered in the presence of personnel who are familiar with this form of medicine. Throughout the period during which you use Livopan you, and administration of the medicine, should be monitored to ensure that it is administered safely. After completion of administration you will be monitored by competent personnel until you have recovered.

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor or nurse if you are not sure. Your doctor or nurse should explain to you how to use Livopan, how Livopan works, and what effects arise from use.

You normally inhale Livopan through a facemask attached to a special valve, which means that you have full control of the flow of gas by virtue of your own breathing. The valve is only open during inspiration. Livopan can also be administered via a so-called nasal mask.

Irrespective of which mask you use, you should breathe normally with normal breaths in the mask.

Use in children

In children that are not capable to understand and follow the instructions, Livopan might be administered under the supervision of competent medical personnel who can help them keep the mask

in place, and actively monitor the administration. In such cases, Livopan may be administered with a constant gas flow.

After you stop using Livopan you should rest and recover until you feel you have recovered mentally.

Safety precautions

- Smoking and open flames are strictly forbidden in rooms where treatment with Livopan is taking place.
- Livopan is intended for medicinal use only

Refer also to instructions for cylinder storage and handling (5. How to store Livopan).

If you use more Livopan than you should

You are very unlikely to receive too much gas, since you govern supply of gas and the gas mixture is fixed, (contains 50% nitrous oxide and 50 % oxygen).

If you breathe quicker than normal and thereby receive more nitrous oxide than you would with normal breathing, you may feel noticeably tired and may to some extent feel out of touch with your surroundings. In such circumstances you should immediately inform the medical staff and stop the administration.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people):

Dizziness, light headedness, euphoria, nausea and vomiting

Uncommon (may affect up to 1 in 100 people):

Severe fatigue. Feeling of pressure in the middle ear, if you use Livopan over a prolonged period. This is because Livopan increases the pressure in the middle ear.

Abdominal bloating, because Livopan slowly increases the volume of gas in the intestines.

Not known: (frequency cannot be estimated from available data)

Effects on nerve function, sensations of numbness and weakness, usually in the legs.

Effects on bone marrow, which can result in anaemia (decreased number of red blood cells) and leukopenia (decreased number of white blood cells).

You can also experience headache and confusion, after cessation of administration.

Psychiatric effects, such as psychosis, confusion, and anxiety has been reported on extremely rare occasions.

Breathing depression

Addiction

Generalised seizures

Reporting of side effects

If you get any side effects, talk to your doctor 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 Livopan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the gas cylinder.

Do not store below -5°C

On suspicion that Livopan has been stored in too cold conditions, the cylinders should be stored in horizontal position at a temperature above +10°C for at least 48 hours before use.

Keep the cylinder in locked storage reserved for medicinal gases.

Keep away from combustible material.

Use only in well-ventilated areas.

No smoking. Must not be exposed to strong heat.

If at risk of fire, move to a safe place. Keep the cylinder clean, dry and free from oil and grease.

Make sure the cylinder is not knocked over or dropped.

Store and transport with valves closed.

Vapour may cause drowsiness and dizziness.

6. Contents of the pack and other information

What Livopan contains

- The active substances are:
nitrous oxide 50% = medicinal laughing gas (chemical term: N₂O) and
oxygen 50%= medicinal oxygen (chemical term: O₂)
- Livopan contains no other ingredients

What Livopan looks like and contents of the pack

Livopan is a colourless, odourless gas without taste, which is supplied in a gas cylinder with a valve to control the gas flow

Pharmaceutical dosage form: medicinal gas, compressed

The shoulder of the gas cylinder is marked in white and blue (oxygen/nitrous oxide). The body of the gas cylinder is white (medicinal gas).

Pack sizes in litres	2	5	10
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Not all pack sizes may be marketed.

Marketing authorisation holder:

Linde Sverige AB

Rättarvägen 3

169 68 Solna

Sweden

Manufacturers

Linde Gas AB
Baltzar von Platens gata 4-6
SE-749 47 Enköping
Sweden

Linde France
16 avenue de la Saudrune
Zone industrielle du Bois Vert
31 120 Portet sur Garonne
France

Linde Gaz Polska Sp. z o.o.
ul. Żwirowa 4
33-100 Tarnów
Poland

LINDE GAZ POLSKA Sp. z o. o.
Oddział w Warszawie
ul. Kasprowicza 132
01-949 Warszawa
Poland

Information supplied by: *To be implemented nationally*

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	LIVOPAN
Belgium	RELIVOPAN
Czech Republic	ENTONOX
Cyprus	ENTONOX
Denmark	LIVOPAN
Estonia	ENTONOX
Finland	LIVOPAN
Germany	LIVOPAN
Greece	ENTONOX
Hungary	LIVOPAN
Iceland	LIVOPAN
Italy	LIVOPAN
Latvia	ENTONOX
Lithuania	ENTONOX
Luxenburg	RELIVOPAN
Netherlands	RELIVOPAN
Norway	LIVOPAN
Poland	ENTONOX
Portugal	LIVOPAN
Romania	ENTONOX
Spain	ENTONOX
Slovakia	ENTONOX

Sweden

LIVOPAN

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Other sources of information

Information on this medicinal product can be found on the website of the Swedish Medicines Agency.
<http://www.lakemedelsverket.se/>.

To be completed nationally

The following information is intended for medical or healthcare professionals only:

Safety directions

No risk for adverse foetal effects has been observed for women occupationally exposed to chronic inhalation of nitrous oxide during pregnancy when an appropriate scavenging or ventilation system is in place. Please see the Summary of Product Characteristics for more information. Special precautions should be taken when working with nitrous oxide. Nitrous oxide should be administered according to local guidelines.

Livopan should only be used in areas that are well ventilated and where there is special equipment to evacuate excess gas. By using a scavenging system and ensuring good ventilation, high atmospheric concentrations of laughing gas in ambient air are avoided. High concentrations of laughing gas in ambient air may cause negative health effects in personnel or other people in the vicinity. There are national guidelines for the concentration of laughing gas that should not be exceeded in ambient air, so-called "hygienic limit values", often expressed as TWA (time weight average), the mean value over a working day and STEL (short-term exposure limit), the mean value during a shorter exposure. These values should not be exceeded in order to guarantee that personnel are not exposed to risk.

Repeated administration or exposure to nitrous oxide may lead to addiction. Caution should be exercised in healthcare professionals with occupational exposure to nitrous oxide.

- The valve should be opened slowly and carefully.
- Turn off the equipment in the event of fire, or if not in use.
- During use the cylinder 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 to leave a small amount of pressure in the cylinder to avoid the entrance of contaminants.
- After use the cylinder valve must be closed hand-tight. Depressurise the regulator or connection.