

Package leaflet: Information for the user

Niontix 100%, medicinal gas, liquefied

Nitrous oxide (medicinal laughing gas)

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

1. What Niontix is and what it is used for.

Niontix is a gas (nitrous oxide – laughing gas) which is used by inhalation. It has a slightly sweet taste and smell and is colourless. It comes in a gas cylinder that has a valve to control gas outflow. The gas cylinder contains pure Niontix under such high pressure that the gas is liquefied.

The effects of Niontix

Niontix produces anaesthetic effects – (sleeping effects) – and when you inhale it, you will become relaxed and tired, which may make you fall asleep.

Niontix has painkilling effects, reduces the sensation of pain, and raises the pain threshold. Niontix 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.

What is Niontix used for?

Niontix is used in all age groups as part of a surgical anaesthetic, or as when painkilling/calming 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.

2. What you need to know before you use Niontix

Niontix is only given to you in a hospital or clinic under the supervision of a healthcare professional. Ensure that your healthcare professional is aware of any medical conditions that you may have.

Do not use Niontix:

- Inhalation of nitrous oxide (Niontix), can cause gas bubbles and enclosed gas filled spaces to expand and thereby cause harm. Therefore do not use Niontix if you:
 - have air in your pleural or heart sack, e.g. due to a disease or injury, a severe type of emphysema e.g. due to smoking, air or gas filled bubbles in your body.
 - recently have been diving with diving equipment and may have risk of decompression sickness.

- recently have been treated in a heart-lung machine.
- recently had a severe head injury.
- If you have recently been treated with a gas injection in the eyeball due to an eye disorder. Increased pressure in the eyes may cause blindness.
- If you have gross abdominal gaseous distension.
- If you have heart failure or severely impaired cardiac function (e.g. after cardiac surgery). Nitrous oxide may cause further impairment of the heart function.
- If you have increased pressure in your brain which may cause confusion or altered consciousness. Nitrous oxide may increase the pressure further.
- If you have decreased level of consciousness or capacity to cooperate and follow instructions when you get nitrous oxide. Nitrous oxide may inhibit protective reflexes.
- If you have diagnosed but untreated vitamin B12 deficiency or folic acid deficiency or have a genetic disorder of the enzyme system involved in the metabolism of these vitamins, since use of nitrous oxide can further increase the deficiency.
- Injuries to the face and jaw, where use of a facemask may present difficulties or risks.

Warnings and precautions

Talk to your doctor or nurse before using Niontix if you have the following signs/symptoms.

- **Cardiac dysfunction**
Since the slightly relaxing effect of nitrous oxide on the heart muscle can further impair cardiac function
- **Ear discomfort**
Such as ear inflammation, since Niontix may increase the pressure in the middle ear.
- **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 Niontix is possible in your case.
- **Vitamin deficiency**
If you are suspected of having vitamin B₁₂ deficiency or folic acid deficiency, since use of Niontix can worsen the symptoms caused by lack of vitamin B₁₂ and folic acid.

Your doctor will decide whether Niontix is a suitable treatment for you.

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 Niontix

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

- Methotrexate, for treating e.g rheumatoid arthritis. Taking Niontix with methotrexate may have an effect on your blood cell count
- If you are taking other medicines which affects the brain or brain function, e.g. benzodiazepines (tranquillising) or morphine like medicines, you should inform your doctor of this. Niontix can increase the effects of these medicines. Niontix in combination with other medicines affecting the central nervous system, increases the effects of these medicines.

Pregnancy, 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.

Niontix 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..

Laughing gas may be used during the breast-feeding period, but should not be used during breast-feeding itself.

Driving and using machines

If you have been given Niontix with Medicinal Oxygen, without any other drug, for safety reasons, you should avoid driving, using machines or carrying out complicated tasks until you are fully recovered. (at least 30 minutes)

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

3. How to use Niontix

Niontix is always administered in the presence of medical staff, who will determine the dose you receive. You should always follow the directions of medical staff when you inhale the gas.

Throughout the period during which you use Niontix, you and the inhalation of the medicine, should be monitored to ensure that it is given/used safely. After completion of the inhalation you will be monitored by competent personnel until you have recovered.

You normally inhale Niontix through a face mask or nasal mask. You either inhale it yourself (“spontaneous respiration”) or you are helped to breathe by a respirator/ventilator, as in anaesthesia. It is given as a gas mixture with oxygen and the doctor will make sure that the oxygen concentration is high enough to avoid oxygen deficiency.

General anaesthesia

When used in general anaesthesia Niontix is combined with other anaesthetics and the concentration needed for an anaesthetic effect is decided by the doctor.

Pain relieving effect and sedation

When used for a pain relieving or calming effects, of rapid onset and rapid resolution, Niontix is inhaled during the entire duration of the procedure or for as long as the pain relieving effect is desired.

Use in children

The doctor will ascertain that an adequate dose is provided and that your child is being carefully monitored because of the potential risk of loss of consciousness and loss of protective reflexes (such as the vomiting reflex) at higher doses.

If you use more Niontix than you should

You should always follow the directions of medical staff when you inhale Niontix.

If you find that you have taken too much Niontix and are affected by shortness of breath (too little oxygen in your blood) or becoming unresponsive, stop using Niontix and tell the personnel.

Depending on the circumstances you may have to breathe ordinary fresh air, or extra oxygen may be administered. The oxygen content of your blood will be continually monitored with the aid of a “pulsioximeter”.

Safety precautions

- Smoking and naked flames are absolutely forbidden in rooms in which laughing gas treatment is being given.
- Niontix (medicinal laughing gas) is intended for medicinal use only.

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

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

- Feeling of pressure in the middle ear. This is because Niontix increases the pressure in the middle ear.
- Abdominal bloating, because Niontix slowly increases the volume of gas in the intestines.

Not known: cannot be estimated from the available data

- Effects on nerve function; sensations of numbness and weakness, usually in the legs
- Breathing depression (shallow and slow breathing)
- Psychiatric effects, such as anxiety and psychosis.
- The following symptoms occur because Niontix affects the quantity of vitamin B₁₂ in the body:

- Low white blood cell counts.
- A specific kind of anaemia called megaloblastic anaemia.

If the doctor suspect vitamin B₁₂ deficiency you may be given vitamin B therapy to minimize the risk of these side effects.

- Headache and confusion, after cessation of administration
- 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 Niontix

This medicinal product does not require any special temperature storage conditions other than those applying to gas containers and gas under pressure.

- Do not smoke or use a naked flame in areas where medicinal gases are stored.
- Cylinders should be stored in a locked and well-ventilated area reserved for the storage of medicinal gases.
- Keep this medicine out of the sight and reach of children.
- Cylinders should be stored under cover, kept dry and clean, kept free from oil and grease, free from combustible material.
- Must not be exposed to strong heat.
- If at risk of fire – move to a safe place.
- Precautions should be taken to prevent blows or falls.
- Cylinders containing different types of gases should be stored separately.
- Full and empty cylinders should be stored separately.
- Store and transport upright with valves closed and, where these are present, with the protective cap and cover in place.

Do not use this medicine after the expiry date which is stated on the cylinder. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Niontix contains

- The active substance is nitrous oxide (laughing gas) 100% (chemical symbol N₂O).
- Niontix contains no other ingredients.

What Niontix looks like and contents of the pack

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

Pack sizes in litres	2.5	4	5	10	20	40	50	12x27	9x50	12x40	12x50
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Not all pack sizes may be marketed.

Marketing Authorisation Holder

Linde Sverige AB
Rättarvägen 3
16968 Solna
Sweden

Manufacturers

Linde Gas AB
Baltzar von Platens gata 4-6
74947 Enköping
Sweden

Linde Gas ehf
Breiðhöfða 11
IS-110 Reykjavík
Iceland

Information provided by

Linde Healthcare (a division of Linde Sverige AB)
Tel.: 08-731 1000.
“To be completed nationally“

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

Denmark: NIONTIX, 100%, medicinsk gas, flydende
Estonia: NIONTIX, 100%, meditsiiniline gaas, veeldatud
Finland: NIONTIX, 100%, lääkkeellinen kaasu, nesteytetty
Iceland: NIONTIX, 100%, lyfjagas, fljótandi
Latvia: NIONTIX, 100%, medicīniska gāze, sašķidrīnāta
Lithuania: NIONTIX, 100%, medicininės dujos, suskystintos
Norway: NIONTIX, 100%, medisinsk gass, flytende
Sweden: NIONTIX, 100%, medicinsk gas, flytande

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To be completed nationally

The following information on this medicine is intended for health care personals only:

Safety directions

- Special precautions should be taken when working with nitrous oxide. Nitrous oxide should be administered according to local guidelines.
- Niontix should be used only in spaces that are well ventilated and/or where special equipment is available which deals with excess gas/exhaled laughing gas. This is in order to avoid excessive concentrations of laughing gas in ambient air, which might affect personnel or other people nearby. There are national guidelines for the concentration of laughing gas that should not be exceeded (“hygienic limit values”).
- Pregnancy: 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.
- Repeated administration or exposure to nitrous oxide may lead to addiction. Caution should be excercised in healthcare professionals with occupational exposure to nitrous oxide.

Handling of the cylinder

- The gas cylinder of Niontix should always be kept upright, with the valve upwards. Although Niontix is a gas when it leaves the cylinder, it takes liquid form inside the cylinder because of pressure. If the cylinder is used lying on its side, liquid may leak out and cause injuries such as frostbite.
- The valve should be opened slowly and carefully to avoid releasing liquefied laughing gas.
- Turn off the equipment in the event of fire or when not in use.
- During use, the cylinder should be fixed in a suitable supporting device.
- The cylinder valve should be closed when a small quantity of gas remains in the cylinder. It is important to leave a small amount of pressure in the cylinder to avoid the entrance of contaminants.
- After use, the cylinder valve should be closed by ordinary hand pressure. Depressurise the regulator or connector.