

Package leaflet: Information for the user

Medicinsk lustgas Nippon Gases Scandinavia 100 %, medicinal gas, liquefied

Nitrous oxide (N₂O)

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

1. What Medicinsk lustgas Nippon Gases Scandinavia is and what it is used for

Medicinsk lustgas Nippon Gases Scandinavia is a medicinal gas that is used for pain relief or, in combination with other anaesthetic agents as an anaesthetic during surgery.

Medicinsk lustgas Nippon Gases Scandinavia is administered by inhalation. When inhaling this medicinal gas you will start feeling relaxed and sleepy, and may fall asleep. Additionally, nitrous oxide has an analgesic effect. The effects of nitrous oxide are caused by its effect on chemical entities in your body called neurotransmitters, which regulates awokeness and perception of pain.

2. What you need to know before you use Medicinsk lustgas Nippon Gases Scandinavia

Do not use Medicinsk lustgas Nippon Gases Scandinavia

- If you:
 - may have air in your pleural sack (pneumothorax), e.g. due to a disease or other reasons
 - recently have been diving with diving equipment
 - may have air or gas filled bubbles in your body (gas embolus)
 - recently have been treated in a heart-lung machine
 - recently had a severe head injuryThe air bubbles may expand during administration of nitrous oxide.
- 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 suffer from severe abdominal discomfort. The symptoms may indicate ileus. Nitrous oxide may increase the intestinal distension.
- If you have a heart disease, e.g. 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 causes confusion or altered consciousness. Nitrous oxide may increase the pressure further.
- If your consciousness or capacity to cooperate decrease when you get nitrous oxide. Nitrous oxide may inhibit protective reflexes.

Warnings and precautions

Talk to your doctor or nurse before taking Medicinsk lustgas Nippon Gases Scandinavia. Inform your doctor if you suffer from any of the following disorders:

- Low vitamin B12 levels. Nitrous oxide may increase the symptoms caused by lack of vitamin B12.
- If you have an ear disorder. Nitrous oxide may increase the pressure in the middle ear.

Other medicines and Medicinsk lustgas Nippon Gases Scandinavia

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

Nitrous oxide may increase the effect of other anaesthetic agents.

Pregnancy and breast-feeding

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

Medicinsk lustgas Nippon Gases Scandinavia may be used when giving birth, but should be used with caution during the first six months of your pregnancy.

Medicinsk lustgas Nippon Gases Scandinavia may be given while you are lactating, but should not be given simultaneously as you are feeding your baby.

Inform your doctor or nurse if you are pregnant or breast-feeding.

Driving and using machines

Medicinsk lustgas Nippon Gases Scandinavia has a sedative effect. You should not drive, operate tools/machines, or perform other demanding activities shortly after using nitrous oxide but wait until the effect has disappeared totally.

3. How to use Medicinsk lustgas Nippon Gases Scandinavia

Administration of Medicinsk lustgas Nippon Gases Scandinavia should always take place under the supervision of health care personnel. Always use this medicine exactly as your doctor or nurse has told you.

Use the gas cylinder in an upright position.

Medicinsk lustgas Nippon Gases Scandinavia is administered in combination with oxygen as a mixture containing at least 21 % oxygen in order to avoid lack of oxygen (hypoxia). The usual dose (concentration) is 35 to 75 volume % nitrous oxide. When used as an anaesthetic, a mixture of nitrous oxide and oxygen will be administered together with other anaesthetic agents.

Medicinsk lustgas Nippon Gases Scandinavia will be given via a mask or a breathing piece. You may inhale the gas by yourself (spontaneous inhalation) or it may be given by means of a respirator or ventilator.

Smoking and open fire are forbidden in rooms where nitrous oxide therapy is being carried out. Medicinsk lustgas Nippon Gases Scandinavia must only be used for medicinal purposes.

If you use more Medicinsk lustgas Nippon Gases Scandinavia than you should

Inform the health care personnel if you get problem breathing. The amount of nitrous oxide will then be reduced or the supply interrupted.

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

4. Possible side effects

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

Common side effects (affects more than 1 out of 100 patients)

Dizziness, feeling of intoxication, nausea, vomiting

Uncommon side effects (affects more than 1 out of 1000 patients but less than 1 out of 100 patients)

Feeling of pressure in the middle ear, bloating, increased gas volume in the bowel

Very rare side effects (affects less than 1 out of 10 000 patients)

Effects on your bone marrow and nervous system, because exposure to nitrous oxide may affect vitamin B₁₂ levels. These side effects are very rare and the risk decreases with decreased period of exposure. If you receive nitrous oxide for a longer period, or very frequently, your doctor may want to take blood samples to monitor your blood levels of e.g. vitamin B₁₂.

Not known side effects (cannot be estimated from the available data)

Generalised seizures

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 Medicinsk lustgas Nippon Gases Scandinavia

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

Do not store above 45 °C.

Store gas cylinders upright in a locked and well-ventilated room reserved for medicinal gases.

Do not expose it to strong heat.

Smoking is not allowed.

Keep the gas cylinder dry and clean, and prevent it from being knocked or dropped.

Gas cylinders should be stored and transported 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 label attached to the gas cylinder. The expiry date refers to the last day of that month.

6. Contents of the pack and other information**What Medicinsk lustgas Nippon Gases Scandinavia contains**

- The active substance is 100 % nitrous oxide.

- Medicinsk lustgas Nippon Gases Scandinavia does not contain any other ingredients.

What Medicinsk lustgas Nippon Gases Scandinavia looks like and contents of the pack

Medicinsk lustgas Nippon Gases Scandinavia is a colourless gas without appreciable odour or taste. It is marketed in a steel cylinder as a colourless liquid under pressure.

Cylinder sizes (litres)	2,5	4	10	40	50	12x40	12x50
Content, gas (kg)	1,9	3.0	7.5	30	37.5	360	450
Content, gas (litres)	1009	1 615	4 035	16 140	20 175	193 680	242 100

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Nippon Sanso Norge AS
P.O. Box 23, Haugenstua
N-0915 Oslo
Norway

Manufacturer

Ijsfabriek Strombeek n.V
Broekstraat 70
BE-1860 Meise
Belgium

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Detailed information on this medicine is available on the web site of [to be completed nationally].

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

If the batch label is missing or is illegible, please do not use the cylinder but return it to Nippon Gases Scandinavia Holdings AS.

General

Medicinal gases must be used for medicinal purposes only.

Never use oil or grease even if the cylinder valve should be stiff or the regulator is difficult to connect. Handle valves and associated devices with clean, grease-free (hand cream etc.) hands.

Use only standard equipment that is designed for medicinal laughing gas (nitrous oxide).

Make sure the cylinders are sealed before they are used.

Be returned with closed valve and remaining pressure at more than 2 bar (200 kPa)

Preparation prior to use

Remove the seal from the valve before use.

Use only regulators designed for nitrous oxide. Check that the attachment on the connector or regulator is clean and that the attachments are in good condition.

Never use tools to tighten a pressure/flow regulator intended to be tightened by hand, since this may damage the connection.

Open the cylinder valve gently, by at least half a revolution.

Do a leakage check in accordance with the instructions accompanying the regulator. Do not attempt to remedy leakage from the valve or equipment other than by changing the gasket or 'O' ring.

If leakage occurs, close the valve and disconnect the regulator. Mark faulty cylinders, put them in the space reserved for rejections and return them to the supplier.

Using the gas cylinder

Smoking and naked flame are absolutely forbidden in rooms in which nitrous oxide treatment is being given.

Turn off the equipment in the event of fire or when not in use.

Remove to a safe place if there is a danger of fire.

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.