

Package leaflet: Information for the user

Medicinal oxygen Nippon Gases Scandinavia 100 %, medicinal gas, cryogenic

Oxygen 100 % (O₂)

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

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1. What Medicinal oxygen Nippon Gases Scandinavia is and what it is used for

Medicinal oxygen Nippon Gases Scandinavia contains oxygen for inhalation. It is colourless, odourless and tasteless and is kept in vessels fitted with a dosing device for regulation of the flow. The vessel contains pure liquified oxygen (cooled to approximately -180°C) (cryogenic gas).

Medicinal oxygen Nippon Gases Scandinavia increases the oxygen content of the blood (increased oxygen saturation). Medicinal oxygen causes the transportation of more oxygen to all tissues in the body.

Medicinal oxygen Nippon Gases Scandinavia is used

- to treat or to prevent acute or chronic oxygen deficit.
- as propellant for the inhalation of other medicines (nebuliser treatment).
- as part of the fresh gas flow in anaesthesia, pain relief and intensive care.
- in hyperbaric chamber to reduce the risk of injury caused by decompression sickness, gas- or air bubbles in the circulation and severe carbon monoxide poisoning, and in gangrene.
- for treatment of acute attack of Cluster headache.

2. What you need to know before you use Medicinal oxygen Nippon Gases Scandinavia

If Medicinal oxygen Nippon Gases Scandinavia is prescribed to you personally, you should inform your doctor if:

- you have a chronic lung disease, for example asthma or COPD

Other medicines and Medicinal oxygen Nippon Gases Scandinavia

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

If you are using other medicines causing possible side effects in the lungs, such as bleomycin (used in cancer), oxygen treatment at the same time may worsen the side effects of these medicines.

Pregnancy and breast-feeding

Medicinal oxygen Nippon Gases Scandinavia can be used during pregnancy.

Medicinal oxygen Nippon Gases Scandinavia can be used during breast-feeding.

3. How to use Medicinal oxygen Nippon Gases Scandinavia

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. You should not change the dose without first consulting your doctor.

Medicinal oxygen Nippon Gases Scandinavia is to be used by inhalation. Normal dose for treating or preventing acute oxygen deficit in adults is 3–4 litres per minute using a nasal canula, or 5–15 litres per minute using a mask. For dosage in other conditions consult your doctor.

Medicinal oxygen Nippon Gases Scandinavia is usually inspired through a nasal canula or a mask. You breathe yourself – “spontaneous inhalation”, or you get help to breathe from a respirator/ventilator.

Carefully read the directions for use/the patient instruction for the oxygen delivery system you use!

If you use more Medicinal oxygen Nippon Gases Scandinavia than you should

In vulnerable situations excess medicinal oxygen can adversely affect the respiratory function and in exceptional cases give rise to carbon dioxide narcosis/unconsciousness.

Long term use of an excess of medicinal oxygen can cause pain, dry cough and even breathlessness.

If these indications of overdosing medicinal oxygen occur always contact a doctor, hospital or the National Poisoning center (phone [to be completed nationally]).

Safety precautions

- Medicinal oxygen Nippon Gases Scandinavia is for medical use only.
- If the label with the batch number is missing or the seal is broken, the cylinder should not be used, but be returned to the supplier.
- Medicinal oxygen Nippon Gases Scandinavia shall be used in well ventilated rooms only.
- Keep the vessel upright. If the vessel tip over cryogenic medicinal oxygen can leak and cause serious frost injuries. During normal use this cold, liquid oxygen makes no harm. When it is released from the vessel it is transformed to oxygen in its usual gaseous form.
- The vessel shall not be exposed to strong heat.
- Smoking and open fire must not occur in rooms where Medicinal oxygen is used, since this will increase the risk of fire.
- Do not use a toaster, hair dryer or similar electrical apparatus during therapy with Medicinal oxygen Nippon Gases Scandinavia.
- Do not put an oxygen mask or nasal canula directly on textiles during treatment – textiles being oxygen saturated can be very liable to catch fire/inflammable. If this yet should happen shake and air such textiles properly.
- Never use grease, oil etc. for lubricating screw threads that jam. These might cause a risk for spontaneous ignition with Medicinal oxygen Nippon Gases Scandinavia.
- Close the equipment when it is not in use.
- In case of fire – close the equipment.
- The vessels shall be moved to a safe place if at risk of fire.
- Handle with care. Ensure that the vessel is not dropped or exposed to knocks.
- Keep the vessel clean and dry.
- Store and transport upright with valves closed.
- Contact with cryogenic oxygen may cause severe burns or frostbite. When handling cryogenic oxygen systems do not allow oxygen or frosted systems to come in contact with the skin or non-protective clothing.

4. Possible side effects

Like all medicines, Medicinal oxygen Nippon Gases Scandinavia can cause side effects, although not everybody gets them.

Treatment outside hospital care

Medicinal oxygen therapy with nasal canula might, because the gas is dry, give rise to dry mucous membranes in the nose and mouth.

Also read the section “*If you use more Medicinal oxygen Nippon Gases Scandinavia than you should*”

Treatment in hospital care

Adverse effects are usually seen with high concentrations (more than 70 %) and after long term therapy (at least 6–12 hours).

- Collapsed pulmonary alveoli
- Respiration related pain and dry cough, acute respiratory distress syndrome (ARDS)

Very rarely the following side effects might occur

- Anemia, effects on the lungs, heart, kidneys and liver.

In the newborn

- Damage to the retina, which might lead to impaired vision, has been regarded as a consequence of therapy with oxygen at concentrations above 40 %.

Side effects from treatment in hyperbaric chamber (hyperbaric oxygen therapy)

- Rupture of the eardrum, sinus pain, reversible muscle pain and effects on the central nervous system ranging from nausea, dizziness, anxiety, confusion and muscle twitching, to unconsciousness and epileptic seizures. Effects on the central nervous system can result from treatment in hyperbaric chamber with more than 2 atmospheres for more than a couple of hours. At higher pressures, symptoms may occur earlier.

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 Medicinal oxygen Nippon gases Scandinavia

Keep out of the reach and sight of children.

Do not store above 45 °C.

Keep the cylinder in a well ventilated place where it is not exposed to strong heat.

Keep the cylinder clean and dry.

Ensure that the cylinder is not dropped or exposed to knocks.

Store separately from combustible material.

Do not use Medicinal oxygen Nippon Gases Scandinavia after the expiry date which is stated on the label attached to the vessel.

6. Contents of the pack and other information

What Medicinal oxygen Nippon Gases Scandinavia contains

- The active substance is oxygen 100 % cryogenic gas (chemical term: O₂)
- Medicinal oxygen does not contain other ingredients.

What Medicinal oxygen Nippon Gases Scandinavia looks like and contents of the pack

Cryogenic vessels for homecare use by patients, sizes:

- (Filled by the patient or health care professionals): 0.3, 0.33, 0.38, 0.5, 0.6, 0.85, 1.2, 1.23
- (Filled by MAH): 10.7, 12, 15, 21, 21.6, 30, 31, 31.2, 36, 38.3, 40, 41, 46, 46.6, 60 and 196 litres.

Stainless steel Mobile Cryogenic vessel with the following capacity: [11.780 kg to 31.690 kg].

The vessels are fitted with a dosing device for selection of the prescribed flow to the patient.

Not all vessel sizes may be marketed.

Marketing Authorisation Holder

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