

AIR LIQUIDE HEALTHCARE

Nitronox 50% Nitrous Oxide and 50% Oxygen Mixture Gas Medicinal

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nitronox. It does not contain all the available information.

It does not take the place of talking to your doctor, anaesthetist, surgeon or dentist.

All medicines have risks and benefits. Your doctor or dentist has weighed the risks of you using Nitronox against the benefits they expect it will have for you.

If you have any concerns about using Nitronox, ask your doctor or dentist.

Keep this leaflet with you, you may want to read it again.

What Nitronox is used for

Nitronox is a gas mixture of 50% Medical Nitrous Oxide and 50% Medical Oxygen used for general anaesthesia.

Nitronox works by relieving pain for certain procedures.

Your doctor may prescribe Nitronox for another purpose. Ask your doctor if you have any questions about why Nitronox has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Nitronox

When you must not use it

Do not use Nitronox if:

1. You have an allergy to nitrous oxide or any other component in the gas or have had an allergic reaction in the past.
2. You have a condition where air is entrapped within your body and it might expand when given Nitronox (eg bowel obstruction, blocked middle ear, following a recent dive). Ask your doctor for full details of these conditions.
3. You have been using it for a prolonged period without proper monitoring of your blood.
4. You are intoxicated or heavily sedated
5. You have recently had any surgery on our eyes or ears where injections of gas have been used.

Do not use Nitronox if the cylinder is damaged or shows signs of tampering or it has degraded.

Before you start to use it

You must tell your doctor or dentist if:

1. You are allergic to any other medicines, foods, dyes or preservatives.
2. You have had a reaction to nitrous oxide or any other

general anaesthetic or pain relief medication in the past.

3. You have had a general anaesthetic or surgery in the past.
4. You have or have had any other health problems or medical conditions, including:
 - A condition known as malignant hyperthermia or a family history of it.
 - Low blood pressure
 - Low vitamin B12 levels
 - Problems with addiction to medicines
 - Bone marrow problems including various cells in the blood
 - Neurological diseases
 - Conditions in which air is entrapped within the body
5. You are pregnant or intend to become pregnant.

Your doctor or dentist will discuss the risks and benefits of using Nitronox when pregnant.

6. You are breastfeeding or wish to breastfeed.

Your doctor or dentist will discuss the risks and benefits of using Nitronox when breastfeeding.

7. Care should be taken when using Nitronox as it is stored under high pressure in gas cylinders. Contact with eyes or skin may result in cold burns. There are also safe working exposure levels and important

storage instructions. Please discuss these with your doctor if you have any questions.

8. You have had long term usage or been chronically exposed to Nitronox.

Taking other medicines

Tell your doctor or dentist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some commonly used medicines that may interfere with Nitronox include:

- Pain relievers
- Anaesthetics
- Methotrexate
- Medicines which may affect your nervous system
- Medicines which may interfere with Vitamin B12 and/or folate metabolism

These medicines may be affected by Nitronox or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Some medicines may affect the way others work. Ask what to do when using Nitronox with other medicines.

Your doctor may have more information on medicines to avoid while using Nitronox.

If you have not told your doctor about any of the above, tell them before you start using Nitronox.

How to use Nitronox

Nitronox should only be used under the supervision of your doctor or dentist.

How much to use and how to use it

The amount of Nitronox given to you will be decided by your doctor or dentist. It is usually given to you by breathing it through a mask.

Follow all directions given to you by your doctor or dentist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor for help.

How long to use it

Your doctor will decide for how long you need to use Nitronox.

If you use too much (overdose)

As Nitronox is most likely to be given to you in hospital under the direction of your doctor, it is very unlikely you will receive an overdose.

However, if this happened, quick action can be taken to maintain your breathing.

If you have any questions then ask your doctor.

After you have used Nitronox

Things you must not do

Following analgesia:

Ask your doctor or dentist when it is safe for you to drive, operate machinery or perform activities following the use of Nitronox.

Side effects

Tell your doctor or dentist as soon as possible if you do not feel well while you are using Nitronox.

Nitronox may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor any questions you may have.

Rare cases of respiratory depression in newborns have been observed, when using nitrous oxide close to delivery, newborns should be supervised for possible side effects.

Tell your doctor or dentist if you notice any of the following and they worry you:

- Nausea, vomiting
- Headache, dizziness, drowsiness

These side effects are usually mild.

Tell your doctor or dentist immediately if you notice any of the following:

- Confusion, excitation and depression of the central nervous system
- Breathing problems
- Anxiety, agitation, disorientation, hallucination
- Heart problems
- Pins and needles, changes in sensation
- Blood disorders
- Seizures
- Abdominal pain, bloating
- Addiction
- impaired vision
- Ear pain
- Vitamin B12 deficiency

These are serious side effects.

You may need urgent medical attention. Serious side effects are rare. Other side effects may occur as a result of your operation or other medications and anaesthetics received so check with your doctor or dentist if you have any concerns.

If any of the above occur, tell your doctor or dentist immediately or go to casualty at your nearest hospital.

Other side effects not listed above may also occur in some patients.

Tell your doctor or dentist if you notice anything else that is making you feel unwell.

Ask your doctor or dentist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Sponsor

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After using Nitronox

Storage

Nitronox is stored at ambient temperature in cylinders by your doctor or hospital under specific instructions.

Disposal

All cylinders are the property of the manufacturer as indicated on the label. All cylinders are returnable to the manufacturer

Product Description

What it looks like

Nitrous oxide is a sweet smelling, colourless, non-irritating gas.

Oxygen is a colourless, odourless gas. Nitronox supplied in a cylinder with a white body and a ultramarine shoulder.

Single cylinders are available in Cylinder sizes C (0.5 m³), D (1.7 m³), E (4.3 m³) and G (8.8 m³).

Ingredients

Active Ingredient

Nitrous oxide- 50%

Oxygen – 50%