

Nitronox Inhalation Gas

nitrous oxide and oxygen

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

- 1 What Nitronox is and what it is used for
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1 What Nitronox is and what it is used for

Nitronox is a breathed in (inhalation) gas. It is a colourless, odourless gas supplied under pressure in a cylinder with a valve to control the flow. The cylinder contains equal amounts of nitrous oxide and oxygen. A variety of cylinder sizes are available.

Nitronox is exclusively for the relief of short-term and intermittent pain. It may be used in the following circumstances:

- at the dentist,
- after an accident,
- during normal child birth,
- during the dressing of wounds and burns.

2 What you need to know before you use Nitronox

Do not use Nitronox:

- If you are allergic to nitrous oxide
- If you suffer from any medical complaint where there is likely to be air entrapped within your body and it might be dangerous for this air to expand such as if you have:
 - been diving recently,
 - decompression sickness,
 - a pneumothorax (air that is trapped next to a lung resulting in collapse of the lung),
 - an air embolism (when bubbles of air become trapped in the circulating blood),
 - a severe form of lung disorder called bullous emphysema,
 - a severely bloated abdomen.

Elderly persons and people with poor vegetarian diets or a history of anaemia should be checked for vitamin B12 deficiency.

Warnings and precautions

Care is needed in the handling and use of Nitronox gas cylinders – you must follow your doctor's instructions.

Fire risks:

- do not smoke or allow those near you to smoke during treatment with Nitronox as it helps things burn.
- do not allow naked flames in the area where you are using your Nitronox, since even the smallest spark can cause violent ignition; electrical equipment capable of sparking (including toys which may produce sparks) must not be used where you are using your Nitronox.

Frequent use or exposure to nitrous oxide may lead to addiction. Therefore take care when using this medicine if you have a history of drug abuse, or work in an environment where you are exposed to nitrous oxide.

When using Nitronox, your doctor will supervise you closely and you may have blood tests to monitor your blood cells.

Other medicines and Nitronox

Tell your doctor if you are taking or have recently taken any other medicines – even those not prescribed. Unless specially advised by your doctor to do so, do not use Nitronox if:

- you are taking or have recently taken **methotrexate** (a medicine used in the treatment of rheumatoid arthritis and in the treatment of tumours)
- you are taking or have recently taken **Vitamin B12**

Pregnancy and breast-feeding

Nitronox can be used for short-term pain relief if you are pregnant, however, seek medical advice before taking any medicine during pregnancy. Nitronox can be used when breast-feeding.

Driving and using machines

You should not drive or use machinery for twelve hours after breathing Nitronox.

Sportsmen and sportswomen

Nitronox will not affect the result of dope testing. However, it is probably best avoided for twelve hours before any sporting event.

3 How to use Nitronox

Nitronox should only be given to you under the direct supervision of attendant and suitably trained medical personnel. Always follow the instructions given by your doctor:

- During use keep cylinders upright, away from heat and in a well ventilated area.
- Connections for hoses, valves, etc must be clean and dry. If necessary clean only with plain water, do not use solvents. Use clean, lint free cloths for cleaning and drying off or similar.
- Nitronox is non flammable but strongly supports combustion (including some materials that do not normally burn in the air). It is highly dangerous when in contact with oils, greases, tarry substances and many plastics.
- If you use Nitronox frequently as advised by your doctor it is

without any significant effects. However, if you are exposed to Nitronox over a longer period it may have severe adverse effects, as may long term exposure to lower levels (i.e. to midwives and nurses who are exposed to it for long periods during their work).

- You should use Nitronox in a well-ventilated area to prevent the build up of exhaled gas.

If the cylinders have been stored below 0°C, then the contents of the cylinder must be re-mixed using one of the following methods:

- 1 Store the cylinder horizontally for 24 hours at or above 10°C;
- 2 Mix the contents by fully inverting the cylinder three times, after warming it at 10°C or more for at least two hours.

You will be given a face mask or mouth piece to use Nitronox. The mask or mouth piece is connected to a Nitronox supply through a demand valve system. You will operate the demand valve by breathing in normally. The valve closes when you stop breathing in or breathe out. You will hold the face mask or mouth piece to your face with your hand and it will remain loose in your hand.

Your doctor may advise a modified method of administration for example using a mouth piece. Follow their instructions.

Your doctor will tell you how much Nitronox you should use per day and how long your treatment with Nitronox is likely to last. Follow your doctor's advice.

If you use Nitronox for more than twenty-four hours, or if you use the gas more frequently than every four days your doctor will take blood tests to check your red and white blood cells. Your doctor will advise when this is necessary.

If you use more Nitronox than you should

If you may have used more Nitronox than you should, talk to a doctor or pharmacist as soon as possible. However, it is very unlikely that an overdose will occur.

4 Possible side effects

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

Feelings of intense happiness, disorientation, sedation, dizziness, tingling and feeling sick are common (may affect up to 1 in 10 people). These minor effects generally reverse rapidly.

Other side effects can include addiction, generalised seizures and effects on the spinal cord and nervous system (myeloneuropathy, neuropathy, or subacute degeneration of the spinal cord). Prolonged or frequent use of nitrous oxide can result in disorders of the red or white blood cells. Prolonged exposure may result in bowel distension and damage to the ears. The frequencies of these side effects are not known (they cannot be estimated from the available data).

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 Yellow Card Scheme, www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nitronox

Check the date given on the batch label attached to the cylinder. Do not use Nitronox after the expiry date which is stated on the label.

- 1 Keep Nitronox out of the sight and reach of children.
- 2 Nitronox should be stored securely in a well-ventilated place, under cover and kept clean and dry.
- 3 Nitronox helps things burn so there must be no smoking or naked flames where the cylinders are stored and the cylinders must not come into contact with oil, grease or some plastics.
- 4 Nitronox cylinders should not be stored where they might suffer extremes of heat or cold, preferably between 10°C and 30°C. If the temperature falls below 0°C it is possible for the gases to separate into nitrous oxide and oxygen. If the cylinders have been stored below 0°C, then please see the instructions under **How To Use Nitronox** above.
- 5 Nitronox cylinders must be stored separately from other medical gases and non-medical gases.

Return empty cylinders to Medical Gas Solutions.

6 Contents of the pack and other information

What Nitronox contains

The active substances are nitrous oxide and oxygen mixed 50:50 v/v.

There are no other ingredients.

What Nitronox looks like and contents of the pack

Nitronox is supplied as a gas in cylinders. These contain compressed gas. The colour scheme for Nitronox cylinders is changing from a blue body with blue and white quartered top to a white body white with a blue and white quartered top. Your cylinder may be of either colour scheme. The cylinder label gives the amount of Nitronox provided by the cylinder when it is used at normal atmospheric pressure. Always read the label.

Marketing Authorisation Holder and Manufacturer

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