

PACKAGE LEAFLET: INFORMATION FOR THE USER
ENTONOX
Oxygen 50%, Nitrous Oxide 50%
Medicinal gas, compressed

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet as you may need to read it again.
- If you have further questions, ask your healthcare professional (doctor, midwife, nurse or pharmacist).
- This medicine has been prescribed for you.
- Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your healthcare professional immediately.

This leaflet gives you information about:

1. What is ENTONOX and what it is used for
2. Things to consider before use
3. How to use ENTONOX
4. Possible side effects
5. How to store ENTONOX cylinders
6. Further Information

1. WHAT IS ENTONOX AND WHAT IT IS USED FOR

ENTONOX is a medicinal gas mixture supplied in cylinders filled to a high pressure. ENTONOX is used to relieve pain during:

- labour in childbirth
- wound cleaning, stitching or dressing
- acute trauma such as broken bones
- other medical conditions or surgical and investigative treatments where pain relief is required.

2. THINGS TO CONSIDER BEFORE USE

ENTONOX is only prescribed to you by a healthcare professional. Ensure that your healthcare professional is aware of any medical conditions that you may have.

Do not use ENTONOX if you have:

- air trapped in a part of the body due to a disease or injury, where its expansion may be dangerous, such as air lodged in an artery
- a collapsed lung
- decompression sickness (the bends) or if you have been deep diving within 48 hours
- lung disease or breathing difficulties such as emphysema
- injuries to the face and jaw
- head injuries
- a severely bloated stomach
- recently consumed alcohol
- suspected or known increased pressure on the brain.

Tell your healthcare professional if you have recently had any surgery on your eyes or ears where injections of gas have been used.

Take special care with ENTONOX

Talk to your doctor or nurse before you are given ENTONOX if you have or have had drug/medication abuse because there is a higher risk of developing dependence to ENTONOX if you take it repeatedly. Your doctor will decide whether treatment with ENTONOX is possible in your case.

Repeated or long-term use of ENTONOX 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.

Tell your healthcare professional if you know you have Vitamin B₁₂ Deficiency.

Inform your healthcare professional if you have accidentally taken Paraquat (a type of weed killer), as there is a possibility of toxic effects to the lungs combined with the high concentration of Oxygen.

Inform your healthcare professional if you have Chronic Obstructive Pulmonary Disease (COPD) or Emphysema, as this may prevent you having ENTONOX due to the oxygen content having an effect on your breathing

Taking other medicines

Please tell your healthcare professional if:

- you are taking Methotrexate for treating arthritis or cancer. Taking ENTONOX with Methotrexate may have an effect on your blood cell count
- you are taking medicines to treat anxiety or help you sleep such as diazepam or lorazepam. These drugs may increase the effect of ENTONOX
- you have been taking or prescribed Bleomycin (to treat cancer) ,Amiodarone (to treat an irregular heartbeat) or Nitrofurantoin and similar antibiotics (to treat infection) before using ENTONOX, as there is a possibility of toxic effects to the lungs due to the high concentration of oxygen.

Tell your healthcare professional, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

ENTONOX can be used for short term pain relief during pregnancy. Ensure that you tell your healthcare professional that you are pregnant before taking ENTONOX as they will advise you on the safe use of ENTONOX.

ENTONOX can be used when breast-feeding.

Driving and using machines

If you have been given ENTONOX on its own for pain relief, it is important that you feel capable before considering whether to drive.

Your healthcare professional will advise you whether it is safe for you to drive

You must wait at least 30 minutes after use before driving or using any machines.

3. HOW TO USE ENTONOX

Instructions for use

In a hospital or clinic ENTONOX will be given to you by a healthcare professional. They will ensure that your ENTONOX supply is suitable for your use and that the equipment has been set up correctly.

To breathe your ENTONOX you will either be given a face mask or mouthpiece. The mask or mouthpiece is connected to a demand valve system which only delivers ENTONOX to you as you breathe in.

ENTONOX will begin to take effect immediately when you start to inhale the gas. The effects of ENTONOX will quickly wear off once you stop breathing the gas. You will be able to control how much ENTONOX you use, depending on the amount of pain you experience.

If you are using ENTONOX at home you will be given full training on the use of the cylinder and equipment when you receive your first supply.

When using your ENTONOX cylinder at home, you must:

- ensure that the cylinder is stood upright on a flat surface and supported so that it will not fall over. Small cylinders may be laid down if appropriate
- check the contents gauge on the cylinder or the regulator before you start to make sure there is enough gas available for your use
- check that the tubing is correctly fitted to the gas outlet
- ensure that all equipment is kept free from oil and grease.
- open the cylinder valve slowly
- turn the cylinder valve 'OFF' with moderate force only when the cylinder is not in use
- if a leak occurs, this will be evident by a hissing noise. Close the cylinder valve and check the equipment
- close the valve with moderate force only when the cylinder is empty.

Always use your ENTONOX exactly as your healthcare professional has shown you. You should check with your healthcare professional if you are not sure.

DO NOT SMOKE or have a naked flame near your ENTONOX gas cylinder. The ENTONOX will make a flame burn much more violently.

NEVER use oil based moisturising creams with your cylinder equipment. If using alcohol gels allow plenty of time for the alcohol gel to dry before handling your cylinder equipment.

If you use more ENTONOX than you should

If you continue to inhale ENTONOX for too long, you will become very drowsy and the mask or mouthpiece will fall away as you relax and hence there is little risk of an overdose with ENTONOX when used correctly.

If you deliberately try to use too much ENTONOX it may eventually result in unconsciousness. If you become unconscious, your ENTONOX supply should be turned off and you should be taken to an area where you can breathe fresh air.

If your breathing has stopped your healthcare professional will provide the appropriate care, mouth to mouth resuscitation or use an oxygen resuscitator if available.

If you are using ENTONOX at home, have someone with you to ensure that you have no difficulties with using the gas. If you take an overdose, you need to stop breathing the ENTONOX and start breathing fresh air. If you do not recover, your helper should call an ambulance and give mouth to mouth resuscitation if your breathing has stopped.

If you have any further questions on how this product is used, ask your healthcare professional.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ENTONOX may cause side effects, although not everybody will get them. Common side effects that may occur if you use ENTONOX are:

- dizziness
- light-headedness
- sickness
- tingling
- disorientation

Less common side effects that may occur if you use ENTONOX are:

- problems with the ear due to increased pressure inside the ear
- tiredness
- bowel enlargement due to trapped gas

Side effects with an unknown frequency that may occur if you use ENTONOX are:

- interference with the way your body uses Vitamin B₁₂, which may affect your blood cell count.
- effects on nerve function including sensations of numbness and weakness, usually in the legs
- difficulty with breathing
- addiction

- generalised seizures

Reporting of side effects

If you experience any of these side effects, or if you notice any side effects not listed in this leaflet, contact your healthcare professional immediately. You can also report side effects directly via HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ENTONOX CYLINDERS

Expiry Date

Do not use ENTONOX after the expiry date which is stated on the cylinder batch label.

ENTONOX cylinders should be used in strict rotation so that cylinders with the earliest filling date are used first

Cylinder Storage

Store your ENTONOX cylinders:

- at a temperature above 10 °C for at least 24 hours before use. If this is not possible D and ED size cylinders should be inverted before use to ensure the gas is completely mixed
- so that they can not fall over and cause injury
- in clean, well ventilated and dry conditions, not exposed to extremes of heat or cold
- away from oil, grease and flammable material
- in a designated area, where they can be kept separate from other medical and non-medical cylinders, with empty and full cylinders kept apart.
- out of sight and reach of children

Handling cylinders

Always handle your ENTONOX cylinders with care, only moving them using an appropriate trolley or handling device.

6. FURTHER INFORMATION

What ENTONOX contains

Your ENTONOX cylinder contains 50% Oxygen and 50% Nitrous Oxide.
There are no other ingredients.

ENTONOX cylinders

ENTONOX medicinal gas, compressed is supplied in the following size cylinders:

Cylinder Size	Cylinder Contents (litres)
D (*)	500
ED	700
F (*)	2000
EX	3500
G(*)	5000
EW	16275

The colour coding of the shoulder of ENTONOX cylinders is blue and white. The body is colour coded white apart from the cylinders marked (*) in the table above which for a limited period may have a blue body

The D, F, G and EW size cylinders need to have a regulator attached to the cylinder valve before the gas can be used. The other cylinders are supplied with an integral pressure regulator built into the cylinder valve.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only

Repeated administration or exposure to ENTONOX may lead to addiction. Caution should be exercised in healthcare professionals with occupational exposure to ENTONOX.