What is in this leaflet?

This leaflet answers some of the common questions about medical nitrous oxide. 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 medical nitrous oxide against the benefits they expect it will have for you. If you have any concerns about using medical nitrous oxide, let your doctor or dentist know.

If any side effect becomes serious, or if you notice any side effects not listed in this leaflet, please see your doctor.

Keep this leaflet. You may need to read it again.

What is medical nitrous oxide and what is it used for?

Medical nitrous oxide is an anaesthesia gas used for pain relief.

It is usually given with another anaesthetic gas and medical oxygen during surgery via a tube placed down your throat by an anaesthetist or given with medical oxygen via a mask by your doctor or dentist.

Medical nitrous oxide works by causing unconsciousness (deep sleep) before and during surgery and by relieving pain for certain procedures.

Ask your doctor if you have any questions about why medical nitrous oxide has been prescribed for you. This medicine is available with a doctor’s prescription only.

Before you use medical nitrous oxide

Contraindications

- When 100% O2 ventilation is required.
- In patients having received recent intraocular injection of gas (such as SF₆, C₃F₈, C₂F₆) as long as an intraocular gas bubble persists and at least for 3 months.
- Nitrous oxide should not be used with any condition where air is entrapped within the body and where its expansion might be dangerous such as:
  - head injuries with impairment of consciousness
  - maxillofacial injuries
  - pneumothorax (artificial, traumatic or spontaneous)
  - air embolism
  - decompression sickness and following a recent dive
  - following a recent underwater dive
  - following air encephalography
  - severe bullous emphysema
  - during middle ear, inner ear and sinus surgery
• gross abdominal distension (e.g. intestinal obstruction)
• if air has been injected into the epidural space to determine the placement of the needle for epidural anaesthesia

Special warnings and precautions for use

• Nitrous oxide should never be given with less than 21% oxygen.
• Nitrous oxide causes inactivation of vitamin B12 (a co-factor of methionine synthase) which interferes with folate metabolism. Thus DNA synthesis is impaired following prolonged nitrous oxide administration. Prolonged or frequent use of nitrous oxide may result in megaloblastic bone marrow changes and possibly myeloneuropathy and subacute combined degeneration of the spinal cord (see also 4.8).
• Nitrous oxide should not be used as an analgesic or anaesthetic agent for more than a total of 24 hours or more frequently than every 4 days, without close clinical supervision and haematological monitoring. Specialist advice should be sought from a haematologist in such cases. Haematological assessment should include an assessment for megaloblastic change in red blood cells and hypersegmentation of neutrophils. Neurological toxicity can occur without anaemia or macrocytosis and with B12 levels in the normal range.
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• In patients with undiagnosed subclinical deficiency of vitamin B12 neurological toxicity has occurred after single exposures to nitrous oxide during general anaesthesia.
• Assessment of vitamin B12 levels should be considered in people with risk factors for vitamin B12 deficiency prior to using nitrous oxide anaesthesia. Risk factors include alcoholic patients, patients suffering from anaemia, or atrophic gastritis, the elderly, those with poor or vegetarian diet.
• At the end of a nitrous oxide/oxygen anaesthesia, withdrawal of the mask leads to an outpouring of nitrous oxide from the lung and consequent dilution of oxygen in incoming air. This results in “diffusion hypoxia” and should be counteracted by giving 100% oxygen for a few minutes when the flow of nitrous oxide is stopped.
• Care should be exercised in the administration of nitrous oxide to patients who have had epidural anaesthesia. If no air has been injected into the epidural space to determine the placement of the needle for epidural anaesthesia, nitrous oxide may be given.
• Scavenging of waste nitrous oxide gas should be used to reduce operating theatre and equivalent treatment room levels to a TWA (Time-Weighted Average) value below 25ppm of ambient nitrous oxide.

Interaction with other medicinal products and other forms of interaction

• The use of nitrous oxide causes inactivation of vitamin B12.
• Administration of nitrous oxide in patients having persistence of intraocular gas bubble after they received intraocular injection of gas and/or patients having received intraocular injection of gas less than 3 months before can cause severe vision impairment caused by expansion of an intraocular gas.

Pregnancy and lactation

• There is no published material which shows that nitrous oxide is toxic to the human foetus. Therefore, there is no absolute contra-indication to its use in the first 16 weeks of pregnancy.
• Medical Nitrous Oxide can be used during lactation.

Effects on ability to drive and use machines
Nitrous oxide is rapidly eliminated but it is recommended that driving, use of machinery and other psycho-motor activities should not be undertaken until 12 hours elapsed after an anesthesia procedure with nitrous oxide use.

Undesirable effects

• Nitrous oxide passes into all gas containing spaces in the body faster than nitrogen passes out. Use of nitrous oxide may result in expansion of non-vented gas containing cavities.

Psychiatric disorders

• Euphoria
• Disorientation
• Addiction to nitrous oxide has been reported.
Gastrointestinal disorders
- Nausea
- Vomiting

Nervous system disorders
- Dizziness
- Paraesthesia
- Myelopathy and/or neuropathy have also been reported following prolonged or frequent use. However in patients with undiagnosed sub-clinical deficiency of vitamin B12, neurological toxicity has occurred after a single exposure to nitrous oxide for anaesthesia.

Blood and lymphatic system disorders
- Prolonged or frequent use of nitrous oxide, including heavy occupational exposure and addiction, may result in megaloblastic anaemia.
- Agranulocytosis has been reported following prolonged nitrous oxide administration.

Eye Disorders
- Severe vision impairment caused by expansion of an intraocular gas (see sections 4.3 and 4.5)

Overdose
- Inappropriate, unwitting or deliberate inhalation of nitrous oxide will ultimately result in unconsciousness, passing through stages of increasing light-headedness and intoxication, and death from anoxia could result.
- Treatment includes: discontinuation of nitrous oxide, removal to fresh air, basic life support, assisted or controlled ventilatory support with medical oxygen and other symptomatic and supportive treatment

Using medical nitrous oxide
Medical nitrous oxide should only be used under the supervision of your doctor or dentist.
The amount of medical nitrous oxide given to you will be decided by your doctor or dentist, depending on the amount of pain relief or sleep required. It is usually given to you by breathing through a mask or by a tube placed down your throat during surgery.
If you are elderly or have lung problems, you may need a lower amount of medical nitrous oxide.
Follow all directions given to you by your doctor or dentist carefully.
Do not take this medicine after the expiry date or if the tamper-evident seal is torn or missing.
Do not use medical nitrous oxide if you notice any significant or unusual damage to the cylinder or its valve.

DO NOT SMOKE
DO NOT PLACE NEAR A FLAME
DO NOT USE OIL OR GREASE ON MEDICAL NITROUS OXIDE EQUIPMENT

Overdose:
As medical nitrous oxide is most likely to be given to you in hospital under the direction of your doctor, it is very unlikely that you will receive an overdose. However, if this happens, quick action can be taken to maintain your breathing and replace the nitrous oxide with more oxygen.

After you have used medical nitrous oxide

- Following general anaesthesia:
Do not drive or operate machinery for at least 24 hours after using medical nitrous oxide.
General anaesthetic may cause a slight decrease in intellectual function and alertness for 2 to 3 days in some people. Ask your doctor when it is safe to drive, operate machinery or perform activities following the use of medical nitrous oxide.

- Following analgesia:
Ask your doctor when it is safe to drive, operate machinery or perform activities following the use of medical nitrous oxide.
Storage

Medical nitrous oxide should be stored by your doctor or hospital in cylinders kept at ambient temperature under specific instructions.

Medical nitrous oxide is a schedule 4 medicine and must be therefore stored in a dedicated area that should be **secured and locked at all times**.

Empty and full cylinders should be stored separately.

Cylinders must be maintained vertically, valve closed.

Cylinders must be protected from impacts and shocks (i.e. bumping into each other or falling). They must be kept away from heat or ignition sources and from temperatures of 55°C and above, from flammable material and stress of weather.

Avoid excessive storage.

Disposal

All AIR LIQUIDE New Zealand cylinders are the property of AIR LIQUIDE New Zealand as detailed on the product label attached to the cylinder, and are to be returned to them when no longer required.

Product description

Medical nitrous oxide is a colourless, gas with a slightly sweet odour.

It is supplied in a variety of cylinder sizes that follow the colour scheme defined by the Australian Standard AS4484.

Ingredients

Medical Nitrous Oxide  ≥ 98.0% v/v

Supplier

AIR LIQUIDE New Zealand Ltd
19 Maurice Road
Penrose, Auckland
Contact: (00) 622-3880

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