MEDICAL NITROUS OXIDE

EP Grade

CONSUMER MEDICINE INFORMATION (CMI)

MEDICAL NITROUS OXIDE
Medicinal gas for inhalation

Please read this consumer information carefully for proper, safe and effective use of your equipment and therapy.

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 anæsthesia gas used for pain relief.

It is usually given with another anæsthetic gas and medical oxygen during surgery via a tube placed down your throat by an anæsthetist 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.

MEDICAL NITROUS OXIDE CYLINDERS ARE EXCLUSIVELY RESERVED FOR THERAPEUTIC USE

Before you use medical nitrous oxide

Contraindications

- When 100% O2 ventilation is required.
- In patients having received recent intraocular injection of gas (such as SF_6, C_3F_8, C_2F_6) 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

Specific to general anesthesia

- Nitrous oxide should never be given with less than 21% oxygen.
- In patients with undiagnosed subclinical deficiency of vitamin B 12 neurological toxicity has occurred after single exposures to nitrous oxide during general anaesthesia.
- At the end of a general anesthesia, when the inhaled fraction of nitrous oxide is above 50%, nitrous oxide withdrawal may lead 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.

Specific to analgesia

- Self-administration should be preferred to allow the assessment of the level of consciousness.
- Attentive monitoring is required in patients taking concomitantly central nervous system depressant drugs and in particular opiates and benzodiazepines, because of the increased risk of deep sedation (see section 4.5)

Common to analgesia and general anesthesia

- Rooms in which nitrous oxide is used must be equipped with a satisfactory scavenging or ventilation system to maintain nitrous oxide levels in the room to a minimum and below any set national occupational exposure limits.
- Nitrous oxide causes inactivation of vitamin B 12 (a co-factor of methionine synthase) which interferes with folate metabolism. Prolonged or frequent use of nitrous oxide may result in megaloblastic marrow changes and myeloneuropathy. Nitrous oxide should not be used without close clinical supervision and hematological monitoring. Specialist advice should be sought from a hematologist in such cases. Assessment of vitamin B12 levels should be considered in people with risk factors for vitamin B12 deficiency prior to using nitrous oxide. Hematological assessment should include assessment for megaloblastic change in red cells and hypersegmentation of neutrophils. Neurological toxicity can occur without anemia or macrocytosis and with vitamin B12 levels in the normal range. There is also evidence that B12 deficiency is associated with depression, organic psychosis. Risk factors may include alcoholic patients, patients suffering from anemia, or atrophic gastritis, those with vegetarian diet, or recent use of medications that interfere with vitamin B12 and/or folate metabolism (see Section 4.5 and 4.8). Vitamin B12 supplements should be given in the case of repeated and prolonged administration.
- In the event of obstruction of the Eustachian tube, an earache and/or middle ear disorders and/or a tympanic rupture may be observed with the increase in pressure in the tympanic cavity (see section 4.8).
- Repeated inhalation of nitrous oxide may lead to addiction. Caution should be exercised in people with a known history of substance abuse of in healthcare professionals with occupational exposure to nitrous oxide. Abuse, misuse and diversion: due to euphoric effects of nitrous oxide (see Section 4.8), nitrous oxide may be sought and abused for recreational use.
- Intracranial pressure must be monitored closely in patients diagnosed and/or at risk of intracranial hypertension as an increase of intracranial pressure (see Section 4.8) has been observed during the administration of nitrous oxide in some patients with intracranial disorders

Paediatric population

Common to analgesia and general anesthesia

- Nitrous oxide may in rare cases cause respiratory depression in the neonate (see Section 4.8). The neonate should be checked for possible respiratory depression when nitrous oxide is used around childbirth.

Interaction with other medicinal products and other forms of interaction

Combinations which are contraindicated

Specific to general anesthesia

- Not applicable

Specific to analgesia

- Not applicable

Common to analgesia and general anesthesia

- Patients having received recent intraocular injection of gas (such as SF6, C3F8, C2F6) as long as an intraocular gas bubble persists or within 3 months after the last injection of an intraocular gas. The expansion of an intraocular gas bubble by nitrous oxide can cause severe visual impairment (see Sections 4.3 and 4.8).

Combinations requiring precautions for use

Specific to general anesthesia

- Not applicable

Specific to analgesia

- Potentialisation of hypnotic effects of central nervous system depressant drugs (opiates, benzodiazepines and other psychotropic drugs) may occur when combined with nitrous oxide (see Section 4.4)

Common to analgesia and general anesthesia

- Medications that interfere with vitamin B12 and/or folate metabolism can potentiate the inactivation of vitamin B12 by nitrous oxide (see Section 4.4 and 4.8).

Fertility, pregnancy and lactation

Specific to general anesthesia

- Not applicable

Specific to analgesia

- Not applicable

Common to analgesia and general anesthesia

Pregnancy**:**

- A large amount of data on pregnant women exposed to a single administration of nitrous oxide during the 1st trimester (more than 1000 exposed outcomes) indicate no malformative toxicity. Moreover no fetal nor neonatal toxicity has been specifically associated with nitrous oxide exposure during pregnancy. Therefore, nitrous oxide can be used during pregnancy if clinically needed. When nitrous oxide is used close to delivery, newborns should be supervised for possible adverse effects (see Sections 4.4 and 4.8).
- In women occupationally exposed to chronic inhalation of nitrous oxide during pregnancy in the absence of appropriate scavenging or ventilation system, an increase in spontaneous abortions and malformations has been reported. These findings are questionable due to methodological biases and exposure conditions, and no risk was observed in subsequent studies when an appropriate scavenging or ventilation system had been implemented (see section 4.4 regarding need for satisfactory scavenging or ventilation system).

Fertility**:**

- No relevant data are available in humans.

Lactation**:**

- There are no data on excretion of nitrous oxide in breast milk. However, after a short-term administration of nitrous oxide, taking into account the very short half life, interruption of lactation is not necessary.

Effects on ability to drive and use machines

Specific to general anesthesia

- Not applicable

Specific to analgesia

- Not applicable

Common to analgesia and general anesthesia

- After stopping administration of nitrous oxide and in particular after prolonged administration, outpatients who must drive or use machines should be monitored until they have recovered the same state of alertness as before administration.

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Undesirable effects

Specific to general anesthesia

- Not applicable

Specific to analgesia
Uncommon (≥1/1,000 to <1/100):

- Nervous system disorders: Excessive sedation.
- Psychiatric disorders: Agitation, anxiety, hallucination, dreams.

Not known (cannot be estimated from the available data):

- Nervous system disorders: Headache

Common to analgesia and general anesthesia

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

Common (≥1/100 to <1/10):

- Gastrointestinal disorders: Nausea, vomiting.

Uncommon (≥1/1,000 to <1/100):

- Nervous system disorders: Paresthesia
- Psychiatric disorders: Euphoria.

Not known (cannot be estimated from the available data):

- Nervous system disorders: Dizziness, myelopathy, neuropathy, intracranial pressure increased and generalised seizures.
- Psychiatric disorders: disorientation
- Blood and lymphatic system disorders: megaloblastic anemia, pancytopenia (observed in predisposing circumstances (cobalamin deficiency, substance abuse)), leucopenia / agranulocytosis (observed after very high and prolonged exposure for tetanus treatment in the 50's).
- Eye disorders: Severe visual impairment (caused by expansion of an intraocular gas.
- Ear and labyrinth disorders: Ear pain, middle ear disorders, tympanic rupture (in the event of obstruction of the Eustachian tube)
- Respiratory, thoracic and mediastinal disorders: Respiratory depression (in the neonate, when nitrous oxide was used during delivery around childbirth.
- Metabolism and nutritional disorders: Vitamin B12 deficiency disorders.
- Addiction

Overdose

Common to analgesia and general anesthesia

- Overdosage may occur after inappropriate storage of EMONO at a too low temperature (see Section 6.4 - the two gases may then dissociate, exposing the patient to a risk of nitrous oxide overdosage). Overdosage could result in increased light-headedness, unconsciousness, cyanosis and death from anoxia. Under these circumstances, treatment should be immediately stopped and appropriate measures should be taken.
- In general anesthesia, in case of overdosage (inhaled nitrous oxide above 70%), hypoxia symptoms could occur. Under these circumstances the inhaled nitrous oxide fraction should be reduced and if appropriate, specific measures should be taken by the anesthesiologist.

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 give 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

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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