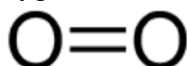


# PRODUCT INFORMATION

## NAME OF THE MEDICINE

MEDICAL EQUANOX (50% Medical Oxygen / 50% Medical Nitrous Oxide)

Oxygen:



CAS number 7782-44-7

MW: 32.0

Nitrous oxide:



CAS number 10024-97-2

MW: 44.01

## DESCRIPTION

**Medical Equanox** is a homogenous gas mixture of Medical Nitrous Oxide 50% v/v and Medical Oxygen 50% v/v.

### Specification - Nitrous oxide

Complies with European Pharmacopoeia specification 1997

Purity	
liquid phase	99.0% minimum
gas phase	98.0% minimum
Carbon dioxide	100 ppm maximum
Carbon monoxide	5 ppm maximum
Higher oxides of nitrogen (NO/NO <sub>2</sub> )	2 ppm maximum
Moisture	60 ppm maximum

### Physical data - nitrous oxide

Molecular weight	44.01
Physical state in cylinder	Gas at ambient Temperature

Specific gravity of gas at 15 C and 101.3 kPa	1.53
Density of gas at 15 C and 101.3 kPa	1.875 kg/m <sup>3</sup>
Combustion characteristics	Non flammable. Strongly supports combustion

Sweet smelling colourless gas  
Boiling point: - 88.60C (at 1 bar)

Nitrous oxide is not very soluble in water but is fifteen times more soluble than oxygen. Water dissolves nitrous oxide, taking 100 volume % and blood plasma 45 volume %.

### Chemical characteristics

Nitrous oxide is an oxidising substance which will support combustion of materials which may not normally burn in air. The molecule is stable and comparatively un-reactive at ordinary temperatures. At elevated temperatures it decomposes to nitrogen and oxygen. Nitrous oxide will react with powerful reducing agents such as phosphine, stannous chloride and hydrogen. Rust may cause ignitions.

### Specification - Medical Oxygen

Complies with European Pharmacopoeia specification 1997

Purity	99.5% (min)
Carbon dioxide	300.0vpm (max)
Carbon monoxide	5.0vpm (max)

### Physical data - Medical Oxygen

Molecular weight	32.00
Physical state in cylinder	Gas
Specific gravity of gas at 15 C and 101.3 mb	1.106
Density of gas at 15 C and 101.3 mb	1.355kg/m <sup>3</sup>
Combustion characteristics	Non flammable. Strongly supports combustion

Excipients: None.

## PHARMACOLOGY

Nitrous oxide is not very soluble in water but is fifteen times more soluble than oxygen. Water dissolves nitrous oxide, taking 100 volume % and blood plasma 45 volume %.

Nitrous oxide is eliminated unchanged from the body mostly by the lungs.

Nitrous oxide is an analgesic and a weak anaesthetic. Pain reduction is achieved at a concentration of around 25%. Induction with nitrous oxide is relatively rapid, but a concentration of about 70% is needed to produce unconsciousness. Endorphins are probably involved in the analgesic effect; a concentration of 25% nitrous oxide is usually adequate to provide a marked reduction in pain.

### Pharmacokinetic properties:

Nitrous oxide at a concentration of 50% (**Medical Equanox**) is a potent analgesic and only slightly soluble. The advantage of this is that when concentrations of not greater than 50% are used, induction of analgesia and recovery occur quickly.

The blood / gas partition coefficient of nitrous oxide at 37° C is 0.46 compared with that of nitrogen of 0.015, causing nitrous oxide to expand into internal gas spaces.

## INDICATIONS

- **Medical Equanox** is used as relief from severe pain, usually in emergency situations;
- Short-term procedures which inevitably involve pain, such as wound and burn dressing, wound debridement and suturing;
- Traumatic injuries;
- Invasive procedures (e.g. catheterisation, sigmoidoscopy)
- Changing position of limbs, manipulation or splinting;
- Altering the position of a patient in pain;
- Applying traction and insertion and removal of skeletal pins for traction;
- Removal of radioactive intracavity gynaecological applicators;
- Physiotherapy;
- Renal colic;
- Labour pains;
- Sternum bone marrow biopsy;
- Constipation;

- Paediatrics;
- In dental work to provide short-term analgesia for tooth extraction and other brief procedures;

## CONTRAINDICATIONS

All these effects are well documented, extremely rare and may follow prolonged exposure to levels of nitrous oxide over 5,000 ppm or to frequent (more than once every two days) exposure to analgesic concentrations. Vitamin B12 in-activations have been reviewed by Nunn.

**Medical Equanox** should not be used with any condition where air is entrapped within a body and where its expansion might be dangerous, such as:

- Head injuries with impairment of consciousness;
- Artificial, traumatic or spontaneous pneumothorax;
- Air embolism;
- Decompression sickness;
- Following a recent dive;
- Following air encephalography;
- Severe bullous emphysema;
- During myringoplasty;
- Gross abdominal distension;
- Intoxication;
- Maxillofacial injuries.

**Medical Equanox** should not be used as an analgesic agent for more than 24 hours without monitoring of peripheral blood for features of megaloblastic anaemia and leukopenia.

## PRECAUTIONS

Administration of **Medical Equanox**, more frequently than every 4 days should be accompanied by routine blood cell counts for evidence of megaloblastic change in red cells and hypersegmentation of neutrophils.

Addiction to nitrous oxide has been reported.

Scavenging of waste nitrous oxide gas should be used to reduce operating theatre and equivalent treatment room levels to a level below 25 ppm of nitrous oxide.

Rescue personnel are advised to monitor nitrous oxide concentration before entering confined spaces and poorly ventilated areas which have been contaminated by an 50% Medical Oxygen/50% Medical Nitrous Oxide leak.

## Long Term Usage

Care should be taken with long term usage of **Medical Equanox**. Chronic exposure to nitrous oxide can inactivate vitamin B12 with resulting neurological and haematological related side effects (See ADVERSE EFFECTS).

### Use with caution in the following circumstances:

Administration of 50% Medical Oxygen/50% Medical Nitrous Oxide more frequently than every four days should be accompanied by routine blood cell counts for evidence of megaloblastic change in red blood cells and hypersegmentation of neutrophils.

Nitrous Oxide passes into gas containing spaces in the body faster than Nitrogen passes out.

### Effects on fertility:

Not applicable.

### Use in pregnancy:

Pregnant females may experience spontaneous abortion and low birth weight babies. Epidemiological studies suggest an increased risk of spontaneous abortion and low birth weight in off-spring in female workers employed in operating theatres and dental surgeries. These findings are controversial.

**Category A:** Drugs which have been taken by a large number of pregnant women and women of childbearing age without a proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

### Use in lactation:

No adverse reports of effects on lactation have been reported/ observed.

### Paediatric use:

Not applicable.

### Use in the elderly

Not applicable.

### Carcinogenicity

Mild skeletal teratogenic changes have been observed on pregnant rat embryos when the dam has been exposed to high concentrations of nitrous oxide during the period of organogenesis. However no increased incidence of foetal malformation has been discovered in 8 epidemiological studies and case reports in human beings.

There is no published material which shows that 50% Medical Oxygen/50% Medical Nitrous Oxide is toxic to the human foetus.

### Genotoxicity:

Not applicable.

**Interactions with other medicines:**

There are no major incompatibilities with 50% Medical Oxygen/50% Medical Nitrous Oxide. 50% Medical Oxygen/50% Medical Nitrous Oxide inactivates vitamin B12.

**Effect on laboratory tests**

Not applicable.

**Effects on ability to drive and to use machines**

50% Medical Oxygen/50% Medical Nitrous Oxide. is rapidly eliminated.

**ADVERSE EFFECTS****Undesirable effects (frequency & seriousness)**

The use of 50% Medical Oxygen/50% Medical Nitrous Oxide causes inactivation of vitamin B12 which is a co-factor of methionine synthase. Folate metabolism is consequently interfered with and DNA synthesis is impaired following prolonged nitrous oxide administration. These disturbances result in megaloblastic bone marrow changes. Exceptionally heavy occupational exposure and addiction have resulted in myeloneuropathy and subacute combined degeneration.

These effects include rarely, drowsiness, confusion, paraesthesia in the legs, hyperflexia and weakness of the intrinsic hand muscles. If these effects occur, usage of **Medical Equanox** should be stopped and daily vitamin B12 replacement administered. Effects should then be expected to be reversed gradually.

All these effects are well documented, extremely rare and may follow prolonged exposure to levels of nitrous oxide over 5,000 ppm or to frequent (more than once every two days) exposure to analgesic concentrations.

It has been suggested that prolonged occupational exposure to high levels of nitrous oxide may affect a woman's ability to become pregnant.

Nitrous oxide passes into all gas containing spaces in the body faster than nitrogen passes out. The main contra-indications which follow from this are listed above, but in addition prolonged anaesthesia may result in bowel distension, middle ear damage and rupture of ear drums.

Addiction to nitrous oxide has been reported.

**DOSAGE AND ADMINISTRATION**

**Medical Equanox** is administered through a face mask or tracheal tube. The gas is breathed in by the patient and absorbed through the lungs.

**Medical Equanox** should only be administered by medical personnel trained in the appropriate techniques.

Cylinders should only be used in conjunction with **Medical Equanox** pressure regulators.

## OVERDOSAGE

Inappropriate, unwitting or deliberate inhalation of nitrous oxide will ultimately result in unconsciousness, passing through stages of increasing light-headedness and intoxication, and if the victim were to be within a confined space, death from anoxia could result.

The treatment is removal of fresh air, mouth-to-mouth resuscitation and, if necessary, the use of an oxygen resuscitator.

## PRESENTATION AND STORAGE CONDITIONS

Pharmaceutical form: Compressed medical gas (for medicinal use only)

**Medical Equanox** is supplied in a gas cylinder with a PIN index valve, suitable for the filling pressure applied for the product.

The types of cylinders normally used are specified in the following table.

Cylinder Size	Nominal water capacity (litres)	Fill pressure (bar)	Fill Volume (m <sup>3</sup> )
C	2.8	120	0.5
D	9.5	120	1.6
E	23	120	4.0
G	50	120	8.0

*Notes:*

*Cylinders conform to AS 2030.1*

*Cylinder valves conform to AS 2473.1 and AS 2473.3*

*The colour code for **Medical Equanox** is an white body with a ultramarine and white triangle shoulder (plus 2 x "N") in accordance with AS4484*

### Instructions for use / handling:

Care is needed in the handling and use of **Medical Equanox** gas cylinders. **Medical Equanox** is stored in high pressure gas cylinders. Cylinders should be used in the vertical position with the valve uppermost.

**Medical Equanox** cylinders must be stored above 0°C. At temperatures below this the nitrous oxide component may separate. Should this occur the cylinder should be placed in a warm room for at least 2 hours, then rolled horizontally to and fro for at least 5 mins to remix the components.

The normal precautions required in the storage and use of medical gas cylinders are applicable. Cylinders should be stored away from sources of ignition, poisons, flammable or combustible materials. They should be secured upright, in a secure area, below 45°C, on a dry well ventilated area constructed of non-combustible material with a firm, level floor (preferably concrete) away from heavy traffic and emergency exits.

Refer to the respective safety data sheet (SDS) and the "caution" section on the product label.

Occupational exposure standard -WorkSafe exposure standard TLV TWA for nitrous oxide is 25 ppm.

**Check the following before use:**

Cylinder should not have been stored below 0° C. See above.

**Medical Equanox** is non-flammable but strongly supports combustion (including some materials which do not normally burn in air). It is highly dangerous when in contact with oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases.

Check that the dispensing equipment connection matches cylinder valve outlet.

Check that the cylinder pressure is a true indicator of quantity remaining in cylinder.

**Preparation for use**

1. Cylinder valves should be opened momentarily prior to use to blow any foreign matter out of the outlet.
2. Ensure that the connecting face on the yoke, manifold or regulator is clean and the sealing washer or 'O' ring where fitted is in good condition.
3. Cylinder valves must be opened slowly.
4. Only the appropriate regulator should be used for the particular gas concerned.
5. Cylinder valves and any associated equipment must never be lubricated and must be kept free from oil and grease.

**Leaks**

1. Should leaks occur this will usually be evident by a hissing noise.
2. Leaks can be found by brushing the suspected area with an approved leak test solution.
3. There are no user serviceable parts associated with these valves, do not attempt to correct any problems with leakage from any part of the valve itself. Label any faulty containers appropriately and return them to Coregas for repair.
4. Sealing or jointing compounds must never be used to cure a leak.
5. Never use excessive force when connecting equipment to cylinders.

**Handling of Cylinders**

1. Cylinders should be handled with care and not knocked violently or allowed to fall.
2. Cylinders should only be moved with the appropriate size and type of trolley.
3. When in use cylinders should be firmly secured to a suitable cylinder support.
4. Cylinders containing liquefiable gas must always be used vertically with the valve uppermost.
5. Medical gases must only be used for medicinal purposes.



6. Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.
7. After use cylinder valves should be closed using moderate force only and the pressure in the regulator or tailpipe released.
8. When empty the cylinder valve must be closed.
9. Immediately return used cylinders to the used cylinder store for return to Coregas.

**STORAGE:**

Cylinders should be kept out of the reach of children.

**Medical Equanox** cylinders must be stored above 0°C.

The normal precautions required in the storage of medical gas cylinders as described below are applicable.

- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- Cylinders should not be stored near stocks of combustible materials or near sources of heat.
- Warning notices prohibiting smoking and naked lights must be posted clearly.
- Emergency services should be advised of the location of the cylinder store.
- Medical cylinders containing different gases should be segregated and identified within the store.
- Full and empty cylinders should be stored separately. Full cylinders should be used in strict rotation.
- Cylinders must not be repainted, have any markings obscured or labels removed.
- D size cylinders and larger should be stored vertically; C size cylinders can be stored horizontally.
- Precautions should be taken to protect cylinders from theft.

**NAME AND ADDRESS OF THE SPONSOR**

Coregas Pty Ltd  
66 Loftus Road  
Yennora NSW 2161  
Australia

**POSITION SCHEDULE OF THE MEDICINE**

**Unscheduled.**

**DATE OF APPROVAL**

**TGA approval: 21/10/1991.**

Date of first inclusion in the Australian Register of Therapeutic Goods: 21/10/1991.

**Date of most recent amendment: 30/05/2013.**

**AUST R: 27141.**