COREGAS Pty Ltd MEDICAL NITROUS OXIDE 100% v/v gas in gas cylinder medicinal gas



Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about having Medical Nitrous Oxide, speak to your healthcare professional or emergency services officer.

1. Why am I having Coregas Pty Ltd Medical Nitrous Oxide?

Coregas Pty Ltd Medical Nitrous Oxide contains the active ingredient Nitrous Oxide. It is used in adults, children and babies mixed with other gases during operations, and it is used together with oxygen to relieve pain. It is also used for other types of procedures such as laparoscopy or, in liquid form, in cryotherapy.

For more information, see Section 1. in the full CMI.

2. What should I know before I have Coregas Pty Ltd Medical Nitrous Oxide?

You will not have Medical Nitrous Oxide if you:

- Are hypersensitive to Nitrous Oxide.
- Are having laser surgery in your airways.
- Have had recent medical treatment (including certain types of eye, ear, brain or heart surgery) or are injured in any way, including face/jaw injury or head injury where you are not conscious.
- Are feeling confused. drowsy or uncoordinated, have heart problems, swollen abdomen, breathing problems or emphysema, cysts, ear problems, have recently been scuba diving and/or have decompression sickness.
- Have a Vitamin B12 or Folic acid deficiency, a genetic predisposition to these or you have a diet lacking in these vitamins.
- Have an embolism (air bubbles) anywhere in your body or a blockage that may lead to an embolism.
- Have had anaemia in the past.
- Are intoxicated.

Talk to the person treating you if you have any other medical conditions including low blood pressure, vitamin B12 or folic acid deficiency or are pregnant or planning to become pregnant or are breastfeeding or planning to breastfeed.

You will only have this if your healthcare professional has said it is OK for you to use it.

For more information, see Section 2. in the full CMI.

3. What if I am taking other medicines?

Tell the person treating you if you are taking any other medicines. See Section 3. in the full CMI.

4. How do I have Coregas Pty Ltd Medical Nitrous Oxide?

You will receive Medical Nitrous Oxide either via a mask or tube during an operation (gas) or via a thin tube directly onto the area being treated (liquid). It is normally given to you by a healthcare professional or emergency services officer. They will decide how much you can have

More information can be found in <u>Section 4</u>. in the full CMI.

5. What should I know while having Coregas Pty Ltd Medical Nitrous Oxide?

Things you should do	Tell the person treating you if you feel that you are not receiving enough Nitrous Oxide, or if you hear a hissing sound coming from the cylinder Make sure your skin is clean and free from oils and grease Be aware that you may have blood tests if you receive Medical Nitrous Oxide for a long time.
Things you must not do	Never smoke or stand near open flames, sparks or high heat. Do not touch any part of the cylinder or equipment with oils or grease, and do not use oil-based moisturisers or creams on your face or nose).

For more information, see Section 5. in the full CMI.

6. Are there any side effects?

If you do experience any side effects, most of them are minor and temporary. The most important side effects that require immediate medical attention include problems breathing, problems thinking clearly, sudden headache, changed mood, feeling confused, euphoric, hyperactive or anxious, twitching, uncontrolled shaking (fits), slow or irregular heart rate, low blood pressure, cold burns if in contact with liquefied nitrous oxide, addiction, problems moving properly. For information about these, and what to do if you get any side effects, see Section 6 in the full CMI.

COREGAS Pty Ltd MEDICAL NITROUS OXIDE 100%v/v gas in gas cylinder medicinal gas

Active ingredient: Nitrous Oxide

Consumer Medicine Information (CMI)

This leaflet provides important information about having Coregas Pty Ltd Medical Nitrous Oxide.

Speak to your healthcare professional or emergency services officer if you want more information, if you are worried or if you have questions about using Medical Nitrous Oxide.

Where to find information in this leaflet:

- 1. Why am I having Coregas Pty Ltd Medical Nitrous Oxide?
- 2. What should I know before I have Coregas Pty Ltd Medical Nitrous Oxide?
- 3. What if I am taking other medicines?
- 4. How do I have Coregas Pty Ltd Medical Nitrous Oxide?
- 5. What should I know while having Coregas Pty Ltd Medical Nitrous Oxide?
- 6. Are there any side effects?
- 7. Product details

<u>For the Healthcare Professional/Emergency Services</u> <u>Officer</u>

1. Why am I having Coregas Pty Ltd Medical Nitrous Oxide?

Coregas Pty Ltd Medical Nitrous Oxide contains the active ingredient Nitrous Oxide. It is a medical gas. It is available only with a prescription.

It is used in adults, children and babies mixed with other gases during operations, and it is used together with oxygen to relieve pain.

It is also used for other types of procedures such as laparoscopy or, in liquid form, in cryotherapy.

2. What should I know before I have Coregas Pty Ltd Medical Nitrous Oxide?

You will not have Medical Nitrous Oxide if you:

- Are hypersensitive to Nitrous Oxide
- Are having laser surgery in your airways
- Have had recent medical treatment (including certain types of eye, ear, brain or heart surgery)
- Are injured in any way, including face/jaw injury or head injury where you are not conscious
- Are feeling confused. drowsy or uncoordinated, have heart problems, swollen abdomen, breathing problems or emphysema, cysts, ear problems, have recently been scuba diving and/or have decompression sickness

- Have a Vitamin B12 or folic acid deficiency, a genetic predisposition to these or you have a diet lacking in these vitamins.
- Have an embolism (air bubbles) anywhere in your body or a blockage that may lead to an embolism.
- Have had anaemia in the past.
- Are intoxicated.

Check with the person treating you if you:

- Have any other medical conditions, including low blood pressure or Vitamin B12 or folic acid deficiency.
- Take any medicines for any other condition.

You will only have this if your healthcare professional or emergency services officer has said it is OK.

During treatment, you may be at risk of developing certain side effects. It is important that you understand these risks and how to watch for them. See additional information under Section 6 Are there any side effects?

Pregnancy and breastfeeding

Tell the person treating you if:

- you are pregnant or planning to become pregnant or
- you are breastfeeding or planning to breastfeed.

They will decide if the benefits of having nitrous oxide. outweigh any risks to the unborn or newborn child. If necessary, you will be given the lowest amount of Medical Nitrous oxide for the shortest possible time.

Medical staff working in areas where Nitrous oxide is used should make sure the area is well ventilated and excess gas extracted (scavenged). There have been reports of reduced fertility in healthcare workers who are repeatedly exposed to Nitrous oxide although it is not known if Nitrous oxide is the cause of this.

Elderly people

Older people may need less Nitrous Oxide, and the amount they use will be increased very gradually.

Children and Babies

Children and newborns, especially premature babies, will be closely monitored by medical staff.

3. What if I am taking other medicines?

Tell the person treating you if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Medical Nitrous Oxide and affect how it works.

4. How do I have Coregas Pty Ltd Medical Nitrous Oxide?

How much to have

Your healthcare professional or emergency services officer will decide how much to have.

Follow their instructions and use Medical Nitrous Oxide until you are told to stop. They will monitor you or your child's treatment and change the amount if needed.

How you will have Coregas Pty Ltd Medical Nitrous Oxide

- You will receive Medical Nitrous Oxide as a gas via a mask or via a tube during an operation.
- If Medical Nitrous Oxide is being given to you as a liquid it will be administered via a very thin tube directly on the area to be treated.
- It is normally given to you by a healthcare professional or emergency services officer.
- Avoid using oil-based moisturisers or creams on your face or nose when using Medical Nitrous Oxide

If you have had too much Medical Nitrous Oxide

If you are conscious, and you think that you have had too much Medical Nitrous oxide, you may need urgent medical attention and the amount of Nitrous oxide you are having will be reduced or stopped. This may be the case if you suddenly feel lightheaded, faint or intoxicated, your heart slows, or you have trouble breathing.

If you come into contact with liquefied Nitrous Oxide you may get a cold burn which will make your skin numb. You may need immediate medical attention. Bathe the area in warm (not hot) water and cover loosely with a sterile dry dressing. Do not smoke or drink alcohol.

You must immediately:

- Tell the person treating you, or
- Go to the Emergency Department at your nearest hospital, or
- Phone the Poisons Information Centre (by calling 13 11 26).

5. What should I know while having Coregas Pty Ltd Medical Nitrous Oxide?

Things you should do

Tell your healthcare professional or emergency services officer straight away if you:

- Feel that you are not getting enough Nitrous Oxide
- Hear a hissing sound coming from the cylinder

Be aware that your blood may be tested for levels of blood components and vitamins, especially if you have to have Nitrous oxide for a few days or longer.

Things you must not do

- You must drink alcohol or not be intoxicated when having this medicine.
- Medical Nitrous Oxide in steel cylinders MUST NOT be used in the same area as MRIs under any circumstances.
- Never smoke or stand near open flames, sparks or high heat while having Medical Nitrous Oxide.
- Do not touch any part of the cylinder or equipment with oils or grease, and make sure your skin is clean and free from oils and grease (this includes not using oilbased moisturisers or creams on your face or nose.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Medical Nitrous Oxide has affected you.

Your doctor will assess you and decide whether you can drive or operate machines.

Drinking alcohol

Tell your healthcare professional or emergency services officer if you have recently drunk alcohol.

Looking after your medicine

Looking after Coregas Pty Ltd Medical Nitrous Oxide is the responsibility of the person or hospital treating you. There are separate instructions for them at the end of this leaflet.

It will be kept where children cannot see or reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Read the following information and, if you need to, ask your doctor or pharmacist if you have any questions about side effects

Less serious side effects

Less serious side effects		What to do
 Feel 	ng dizzy, light-headed or	
slee	ру	Speak to your
 Feel 	ng bloated	healthcare
• Feel	ng or being sick	professional or
• Prob	lems hearing or pain in	emergency
your	ears	services officer if
• Head	dache	you have any of
• Num	bness in your hands and	these side effects
legs	problems flexing hand	and they worry
mus	cles; muscle weakness	you.

Serious side effects

Serious side effects	What to do
 Problems when breed sudden headache, of sudden headache, of mood, feeling confusions. twitching, uncontrous shaking (fits) slow or irregular head low blood pressure. cold burns if in confusions of liquefied nitrous ox addiction to nitrous problems moving public low levels of red or blood cells 	call the healthcare professional or emergency services officer straight away if you are already in hospital, otherwise go straight to the Emergency Department at your nearest hospital.

Tell the person treating you if you feel unwell in any way.

Other side effects not listed here may occur in some people. Be aware that some people have abused nitrous oxide, and some people have become addicted to nitrous oxide.

Reporting side effects

After you have received medical advice for any side affects you may have had, you can report these side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is normally supplied for use in hospitals, dental surgeries or in emergency situations.

What Coregas Pty Ltd Medical Nitrous Oxide contains

Active ingredient	Nitrous Oxide gas
(main ingredient)	
Other ingredients	None
(inactive ingredients)	
Potential allergens	None

What Coregas Pty Ltd Medical Nitrous Oxide looks like

Coregas Pty Ltd Medical Nitrous Oxide has a sweet smell and no colour.

The cylinders have a white body and ultramarine shoulder. They are made of either steel or aluminium and sealed with a Pin Index valve outlet.

Single cylinders that are used for administering liquid nitrous oxide have a different outlet and contain a dip tube.

They may be available in the following pack sizes:

Cylinder Size	Water
	Volume
	(litres)
С	2.8
D	9.5
E	23
G	50
6 Pack*	300
12 Pack**	600

^{* 6} Pack (bundles) of 6x 50 L Size G cylinders

(Not all pack sizes or presentations may be available)

Who distributes Coregas Pty Ltd Medical Nitrous Oxide?

Coregas Pty Ltd 66 Loftus Road Yennora NSW 2161 Australia

Email: <u>Customer.services@coregas.com</u>

Phone: 1800807203

Website: www.coregas.com.au/healthcare

Aust R 27183.

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^{** 12} Pack (bundles) of 12x50 L Size G cylinders

For the Healthcare Professional/Emergency Services Officer

Instructions for use/handling

Please refer to the Product Information for full safety information.

- Coregas nitrous oxide is a simple asphyxiant in the absence of oxygen.
- Care is needed in the handling and use of Medical Nitrous Oxide gas cylinders.
- Refer to the respective S.D.S, the Product Information and the "caution" sections of the product label.
- Check the following before use:
 - Sources of ignition (avoid contact with or close proximity with open flames or sparks, oils, greases, tarry substances, plastics)
 - Operability of oxygen mixing apparatus and availability of oxygen
 - O Dispensing equipment matches cylinder valve outlet (there are different outlets for cylinders supplying gas and cylinders supplying liquid nitrous oxide)
 - Quantity in cylinder (measure contents by weight rather than rely on cylinder pressure).

Occupational Exposure

- Nitrous oxide is classified as hazardous according to criteria of Worksafe Australia. Worksafe exposure standard TLV TWA
 is 25 ppm.
- Professionals chronically exposed to nitrous oxide should have a regular full blood examination.
- It is important that the nitrous oxide content in the ambient air is kept as low as possible and well below the nationally set limit value.
- 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.
- While a causal connection has not been established, reduced fertility in medical and paramedical personnel has been reported after repeated exposure to nitrous oxide in inadequately ventilated rooms.
- Chronic exposure to nitrous oxide may lead to bone marrow or neurological impairment
- Rescue personnel are advised to monitor nitrous oxide concentration before entering confined spaces and poorly ventilated areas which have been contaminated by a nitrous oxide leak.
- Suitable manual handling equipment should be used to transport cylinders.
- Accidental inhalation or cold burns should be treated immediately even if there Is no immediate effect on the person
 exposed. Accidental inhalation should be treated with fresh air and resuscitation if needed. Superficial cold burns may
 initially be treated by immersion in lukewarm water and use of dry sterile dressings; if extensive then hospital attention is
 required.

Use

- Do not use this product if the cylinder is damaged or the tamper evident seal has been removed.
- Nitrous oxide is stored in high pressure gas cylinders as a liquid under pressure at ambient temperature.
- Check the cylinder label and valve outlet to distinguish between cylinders for administering gases and cylinders for administering liquid nitrous oxide.
- In standard operation, the package is designed to deliver product in gaseous form, however rapid opening of the valve and sustained high flow rates can cause the discharged gas to re-liquefy. This liquid can cause cold burns if in contact with the eyes and skin.
- Cylinders should be used in the vertical position with the valve uppermost. If not liquid may be discharged when the valve is opened.
- When Medical Nitrous Oxide is intended for use in a room in which magnetic resonance imaging (MRI) is being performed, all steel medical Nitrous Oxide cylinders and associated equipment must be considered to potentially contain ferromagnetic materials. Steel cylinders do contain a substantial quantity of ferromagnetic material and MUST NOT be used in proximity to MRIs under any circumstances.
- Electrical equipment capable of sparking or generating extreme heat should not be used in the vicinity of patients receiving Medical Nitrous Oxide.
- Under no circumstances should oils or grease be used to lubricate any part of the medicinal Nitrous Oxide cylinder or the associated equipment used to deliver the gas to the patient. Always ensure hands are clean and free from any oils or grease.
- Where moisturising preparations are required for use with a facemask., avoid using oil-based creams.
- Where alcohol gels are used to control microbiological cross-contamination ensure that all alcohol has evaporated before handling

- Use gas cylinders with suitable pressure reducing regulator.
- Medical gases must only be used for medicinal purposes
- Refer to manufacturer for cleaning guidelines.
- All regulations concerning handling of pressure vessels must be followed.
- Cylinders should be handled with care. They must not be allowed to fall or subjected to violent impact. If, after an accidental collision, a cylinder exhibits local deformation or a notch, even shallow, it should be considered as hazardous and removed from use. It must be returned to the supplier with notification of the damage.
- Cylinders should only be moved with the appropriate size and type of cylinder trolley (pallet jack).
- Smoking and naked lights must not be allowed within the vicinity of cylinders or pipeline outlets.
- After use cylinder valves should be closed using moderate force only and the pressure in the regulator, manifold, etc released.
- Immediately return used cylinders to the used cylinder store for return to Coregas.
- Do not keep cylinders after their expiry date.

Storage

- Medical Nitrous Oxide cylinders should be kept out of the reach of children.
- They should not be near heavy traffic or emergency exits
- Cylinders should not be stored near stocks of flammable or combustible materials, poisons or sources of ignition. It is highly
 dangerous when nitrous oxide comes into contact with oils, greases, tarry substances and many plastics due to the risk of
 spontaneous combustion.
- The cylinders will be stored so they are upright, secure and on a firm, level floor, where the temperature does not go above 45°C.
- Warning notices prohibiting smoking and naked lights must be posted clearly.
- The normal precautions required in the storage of medical gas cylinders as described below are applicable.

Standard storage Instructions for Medical Nitrous Oxide Cylinders

- Emergency services should be advised of the location of the cylinder store.
- Cylinders should be stored under cover, preferably inside, kept dry and clean and not subjected to extremes of heat or cold.
- Medical cylinders should be segregated by medical gas type and identified as such within the store.
- Full and empty cylinders should be stored separately. Full cylinders should be used on a "first in / first out" basis.
- Cylinders must not be re-painted. Cylinder markings must not be obscured. Product labels must not be removed. Foreign objects and attachments must not be affixed when returning cylinders. All gas cylinders should be stored vertically.
- Precautions should be taken to protect cylinders from theft and / or interference.
- Cylinders must be stored in storage area specially provided for the purpose. The storage area must be ventilated.
- If they are placed along a personnel passageway, they must be prevented from falling by means of chains.
- Whether empty or full, all cylinders in the storage area must be equipped with their valve protection caps and valve closed.

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