

## **Package leaflet: Information for the user**

### **Donopa, 50 %/50 % v/v, medicinal gas, compressed** Nitrous oxide / Oxygen

**Read all of this leaflet carefully before you start using this medicine, because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Donopa is and what it is used for
2. What you need to know before you use Donopa
3. How to use Donopa
4. Possible side effects
5. How to store Donopa
6. Contents of the pack and other information

#### **1. What Donopa is and what it is used for**

Donopa contains a ready mixture of nitrous oxide (N<sub>2</sub>O) and oxygen (medicinal oxygen, O<sub>2</sub>), 50% of each, and should be used by breathing in the gas mixture.

Donopa can be used in adults and children older than 1 month.

#### **The effects of Donopa**

The nitrous oxide constitutes 50% of the gas mixture. Nitrous oxide has a painkilling effect, reduces the sensation of pain, and raises the pain threshold. Nitrous oxide also has a relaxing and slightly calming effect. These effects are produced by the effects of nitrous oxide on signal substances in your nervous system.

The effect of Donopa is lower in children who are less than three years old.

The 50-percent concentration of oxygen, around double that in ambient air, guarantees a safe oxygen content in the inspired gas.

### **Donopa should be used**

- When painkilling effects that start quickly and stop quickly are wanted and when the treated pain state is of mild to moderate intensity and of limited duration. Donopa produces painkilling effects after just a few breaths and the painkilling effects subside within minutes after use is ceased.
- For dental care, in anxious patients.

## **2. What you need to know before you use Donopa**

### **Do not use Donopa:**

Before you use Donopa you should inform your doctor if you have any of the following signs/symptoms:

- **Gas-filled cavities or gas bubbles:** if as a result of illness, or for any other reason it may be suspected that there is air in your chest outside the lungs, or gas bubbles in your blood or any other organ. E.g. if you have dived with diving equipment and may have gas bubbles in your blood, or if you have been treated with an injection of gas into the eye, e.g. for a retinal detachment or similar. These gas bubbles may expand and thereby cause harm.
- **Heart disease:** if you have heart failure or severely impaired heart function, since the slightly relaxing effect of nitrous oxide on the heart muscle can further impair cardiac function.
- **Central nervous system injury:** If you have increased pressure in the brain, e.g. resulting from a brain tumour or bleed in the brain, since nitrous oxide can further increase the pressure in the brain with potential risk of harm.
- **Vitamin deficiency:** If you have been *diagnosed with* vitamin B<sub>12</sub> deficiency or folic acid deficiency (including in early pregnancy) but have not been treated for this, since use of nitrous oxide can worsen the symptoms caused by vitamin B<sub>12</sub> and folic acid deficiency.
- **Ileus:** If you have severe abdominal discomfort: symptoms which may indicate ileus, then Donopa may further increase the dilation of the gut.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Donopa if you:

- have or have had drug/medication abuse because there is a higher risk of developing dependence to nitrous oxide if you take it repeatedly. Your doctor will decide whether treatment with Donopa is possible in your case.

Repeated or long-term use of nitrous oxide may increase the risk of vitamin B<sub>12</sub> 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 B<sub>12</sub> deficiency.

Also inform your doctor if you have any of the following signs/symptoms:

- **Ear discomfort:** e.g. ear inflammation, since Donopa may increase the pressure in the middle ear.
- **Vitamin deficiency:** If you are *suspected* of having vitamin B<sub>12</sub> deficiency or folic acid deficiency, since use of nitrous oxide can worsen the symptoms caused by vitamin B<sub>12</sub> and folic acid deficiency.
- The success rate is lower in children under 3 years.

You must breathe normally during inhalation.

Your doctor will decide whether Donopa is suitable for use.

### **Other medicines and Donopa**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you are taking other medicines which affects the brain or brain function, e.g. benzodiazepines (tranquillising) or morphine like medicines, you should inform your doctor of this. Donopa can increase the effects of these medicines. Donopa in combination with other sedatives, or other medicines affecting the central nervous system, increases the risk of side effects.

You should also inform your doctor if you are taking medicine containing methotrexate (e.g. for rheumatoid arthritis), bleomycin (to treat cancer), furadantin or similar antibiotics (to treat infection) or amiodarone (to treat heart disease). Donopa increases the side effects of these medicines.

### **Pregnancy, breast-feeding and fertility**

Donopa can be used during pregnancy if clinically needed.

After a short-term administration of Donopa, interruption of breast-feeding is not necessary.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

If you have been given Donopa, without any other painkilling/sedative drug, for safety reasons, you should avoid driving, using machines or carrying out complicated tasks until you are fully recovered (at least 30 minutes).

Ensure that your healthcare professional advises you whether it is safe for you to drive.

## **3. How to use Donopa**

Donopa will always be given to you in the presence of personnel who are familiar with this form of medicine. They will ensure that your Donopa supply is suitable for use and that the equipment has been set up correctly. While you are using Donopa you will be monitored to ensure that you take it safely. After you stop using Donopa you will be monitored by competent personnel until you have recovered.

Always use this medicine exactly as your doctor has told you.

Your doctor should explain to you how to use Donopa, how Donopa works, and what effects arise from use. Check with your doctor if you are not sure.

You normally breathe in Donopa through a facemask attached to a special valve, which means that you have full control of the flow of gas by virtue of your own breathing. The valve is only open while you are breathing in. Donopa can also be administered via a so-called nasal mask.

Irrespective of which mask you use, you should breathe normally with normal breaths in the mask.

After you stop using Donopa you should rest and recover until you feel you have recovered mentally.

### **Safety precautions**

- Smoking and open flames are strictly forbidden in rooms where treatment with Donopa is taking place.
- Donopa is intended for medicinal use only.

### **If you use more Donopa than you should**

You are very unlikely to receive too much gas, since you govern supply of gas and the gas mixture is fixed (contains 50% nitrous oxide and 50% oxygen).

If you breathe quicker than normal and thereby receive more nitrous oxide than you would with normal breathing, you may feel noticeably tired and may to some extent feel out of touch with your surroundings. In such circumstances you should immediately inform the medical staff and stop the administration.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Common** (may affect up to 1 in 10 people)

Dizziness, light headedness, euphoria, nausea and vomiting.

### **Uncommon** (may affect up to 1 in 100 people)

Severe fatigue. Feeling of pressure in the middle ear, if you use Donopa over a prolonged period. This is because Donopa increases the pressure in the middle ear.

Abdominal bloating, because Donopa slowly increases the volume of gas in the intestines.

### **Not known** (frequency cannot be estimated from available data)

Effects on bone marrow, which can result in anaemia.

Effects on nerve function, sensations of numbness and weakness, usually in the legs.

This is because nitrous oxide affects vitamin B<sub>12</sub> and folate metabolism and thereby inhibits an enzyme: methionine synthetase.

Abnormal movements generally occurring after hyperventilation (*increase in breathing rate during inhalation*).

Breathing depression. You can also experience headache.

Psychiatric effects, such as psychosis, confusion, anxiety, addiction.

Generalized seizures.

### **Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. 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](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

## **5. How to store Donopa**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the cylinder batch label. The expiry date refers to the last day of that month.

Store between 0°C and 50°C. Do not freeze.

On suspicion that Donopa has been stored in too cold conditions, the cylinders should be stored in horizontal position at a temperature above +10°C for at least 48 hours before use.

Keep away from combustible material.

Contact with combustible material may cause fire.

No smoking or naked flames near Donopa.

Must not be exposed to strong heat.

If at risk of fire – move the cylinder to a safe place.

Keep the cylinder clean, dry and free from oil and grease.

Keep the cylinder in locked storage reserved for medicinal gases.

Store and transport with valves closed.

Make sure the cylinder is not knocked or dropped.

Inhaling vapour may cause drowsiness and dizziness.

## **6. Contents of the pack and other information**

### **What Donopa contains**

- The active substances are:  
nitrous oxide 50% (v/v) (chemical term: N<sub>2</sub>O) and oxygen 50% (v/v) = medicinal oxygen (chemical term: O<sub>2</sub>).
- Donopa contains no other ingredients.

### **What Donopa looks like and contents of the pack**

Donopa is a colourless, odourless gas without taste, which is supplied in a gas cylinder with a

valve to control the gas flow. The cylinder can either be made of steel or aluminium.  
Pharmaceutical dosage form: medicinal gas, compressed  
The shoulder of the gas cylinder is marked in white and blue (oxygen/nitrous oxide). The body of the gas cylinder is white (medicinal gas).

Pack sizes in litres (135 bar)	2	2.7	5	10	15	20
Pack sizes in litres (185 bar)	2		5			

Not all pack sizes may be marketed.

**Marketing authorisation holder**

SOL SpA  
Via Borgazzi, 27  
20900 Monza  
Italy

**Manufacturer**

SOL France  
ZI des Béthunes  
8 Rue du Compas  
95310 Saint Ouen l'Aumone  
France

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria: Donopa  
Belgium: Antafil, 50%/50% v/v, gaz médicinal comprimé  
Bulgaria: Донопа  
Croatia: Donopa  
Germany: Donopa  
Greece: Donopa  
Hungary: Donopa  
Ireland: Donopa  
Italy: Donopa  
Luxemburg: Antafil  
Netherlands: Donopa  
Slovenia: Donopa  
Spain: Donopa  
UK: Donopa

**This leaflet was last revised in 11/2022**

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**The following information is intended for healthcare professionals only:**

**Safety directions**

Repeated administration or exposure to nitrous oxide may lead to addiction. Caution should be exercised in healthcare professionals with occupational exposure to nitrous oxide. Nitrous oxide should be administered according to local guidelines. Donopa should only be used in areas that are well ventilated and where there is special

equipment to evacuate excess gas. By using a scavenging system and ensuring good ventilation, high atmospheric concentrations of nitrous oxide in ambient air are avoided. High concentrations of nitrous oxide in ambient air may cause negative health effects in personnel or other people in the vicinity. There are national guidelines for the concentration of nitrous oxide that should not be exceeded in ambient air, so-called “hygienic limit values”, often expressed as TWA (time weight average), the mean value over a working day and STEL (short-term exposure limit), the mean value during a shorter exposure. These values should not be exceeded in order to guarantee that personnel are not exposed to risk.

- The valve should be opened slowly and carefully.
- Turn off the equipment in the event of fire, or if not in use.
- During use the cylinder must be fixed in a suitable support.
- One should consider replacing the gas cylinder when the pressure in the bottle has dropped to a point where the indicator on the valve is within the yellow field.
- When a small quantity of gas is left in the gas cylinder, the cylinder valve must be closed. It is important to leave a small amount of pressure in the cylinder to avoid the entrance of contaminants.
- After use the cylinder valve must be closed hand-tight. Depressurise the regulator or connection.