

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using INOMax?

INOMax contains the active ingredient nitric oxide. INOMax is used to treat babies who have been born near (34 weeks) or at term and who have been diagnosed with a condition called hypoxic respiratory failure. INOMax may also be given to patients who are having or just had, heart surgery and develop high blood pressure in the lungs.

For more information, see Section [1. Why am I using INOMax?](#) in the full CMI.

### 2. What should I know before I use INOMax?

Do not use if you have ever had an allergic reaction to INOMax or any of the ingredients listed at the end of the CMI.

INOMax should not be used if you or your baby has any history of hypersensitivity to inhaled nitric oxide.

**Exposure to INOMax during pregnancy and breast-feeding should be avoided.**

For more information, see Section [2. What should I know before I use INOMax?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with INOMax and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use INOMax?

- INOMax is administered by a specialist doctor in a hospital through a system designed for delivering nitric oxide.
- Your doctor will administer INOMax at the dose and duration of treatment required for your condition.

More instructions can be found in Section [4. How do I use INOMax?](#) in the full CMI.

### 5. What should I know while using INOMax?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using INOMax.</li><li>• Contact your doctor if you become pregnant or experience an allergic reaction.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use INOMax if you have any history of hypersensitivity to inhaled nitric oxide.</li><li>• Do not use INOMax if you are pregnant or breast-feeding.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• You should not drive or operate machinery immediately following treatment.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• You should not drink alcohol while using INOMax particularly if you have some other diseases.</li><li>• Discuss further with your doctor or pharmacist.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• INOMax is administered in a hospital and will be stored in the hospital pharmacy.</li></ul>

For more information, see Section [5. What should I know while using INOMax?](#) in the full CMI.

### 6. Are there any side effects?

When nitric oxide is inhaled it may cause the red blood cells to have less capacity to carry oxygen. It can also be harmful in other ways to the lungs. The doctor should be monitoring the blood for these and other side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# INOmax<sup>®</sup>

Active ingredient(s): nitric oxide

## Consumer Medicine Information (CMI)

This leaflet provides important information about using INOmax. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INOmax.**

### Where to find information in this leaflet:

- [1. Why am I using INOmax?](#)
- [2. What should I know before I use INOmax?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use INOmax?](#)
- [5. What should I know while using INOmax?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using INOmax?

The active ingredient in INOmax is nitric oxide. INOmax can improve the flow of blood through the lungs and reduce blood pressure in the lungs by relaxing the cells around the blood vessels and allowing these blood vessels to widen. This may help to increase the amount of oxygen that reaches the blood stream.

INOmax is used to treat:

- 1) Near term(>34 weeks) or term babies with hypoxic respiratory failure.** A baby with hypoxic respiratory failure has less blood flow through the lungs, and low amounts of oxygen in the blood. Some medical conditions, such as pulmonary hypertension (high blood pressure in the lung), meconium aspiration (stained amniotic fluid in the lungs) and infection, may cause hypoxic respiratory failure.
- 2) Children or adults undergoing Heart Surgery.** INOmax may be given in patients who are having, or just had, heart surgery and develop high blood pressure in the lungs. In these patients, INOmax is used to help reduce blood pressure in the lungs.

Before your doctor prescribes INOmax, other types of therapy may be given to try to improve your condition. If these other therapies do not improve your condition, INOmax may be given.

INOmax is a 'PRESCRIPTION ONLY MEDICINE.' It is to be given only to the person for whom it has been prescribed.

## 2. What should I know before I use INOmax?

### Warnings

#### Do not use INOmax if:

- Babies who are dependent on an abnormal circulation within the heart
- Any history of hypersensitivity to inhaled nitric oxide.

#### Check with your doctor if you:

- Are pregnant or if there is a chance you may be pregnant or intend to become pregnant.
- Breast-feeding
- Have abnormal heart function  
In patients whose hearts are less efficient than normal at pumping blood around the body, nitric oxide can increase the chance of serious side effects occurring, such as the build up of fluid in the lungs due to a blocked or narrow vein in the lung, worsening of abnormal heart function, low blood pressure, abnormally slow heart beat, and stopping of the heart. For these patients, the doctor will weigh up the risks of using INOmax<sup>®</sup> against the benefits it is expected to provide.

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

### Pregnancy and breastfeeding

Exposure to INOmax<sup>®</sup> during pregnancy and breast-feeding should be avoided.

## Use in children

INOMax is intended for the treatment of babies who are near term (>34 weeks) or at term and children who are undergoing heart surgery.

## Use in the elderly

There is no evidence of a requirement for reduction in frequency or duration of treatment with INOMax in elderly patients.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist 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 INOMax and affect how it works.

Some medicines can affect the blood's ability to carry oxygen. The doctor will decide when to treat with INOMax® and with other medicines and will carefully supervise the treatment.

### Effects of INOMax on other medicines

Some medications may interfere with INOMax, because they are inactivated by the same mechanism as INOMax or because they bind to the same body structures as INOMax.

### Medicines that may increase the effects of INOMax include:

- Nitroglycerine, sodium nitroprusside
- Vasodilators such as sildenafil, surfactants, prilocaine, alkyl nitrates and sulphonamides

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INOMax.**

## 4. How do I use INOMax?

### How much to use

This medicine is always administered by a specialist doctor who can explain exactly what is happening. The doctor will decide how many treatment sessions you need.

INOMax must be diluted before use. Your doctor will closely monitor the delivery system used to administer INOMax.

Your doctor will decide the correct dose of INOMax and will administer INOMax to the lungs through a system designed for delivering nitric oxide. This system delivers the correct amount of INOMax to the lungs by diluting INOMax with an oxygen / air mixture before delivery.

For your safety, the delivery system intended for administration of INOMax® are fitted with devices that

constantly measure the amount of nitric oxide, nitrogen dioxide, and oxygen being delivered to the lungs. In addition, blood will be tested throughout the treatment period to make sure there is no interference with the ability of the blood to carry oxygen.

Because side effects increase with higher doses of inhaled nitric oxide therapy, you will be given a low dose of INOMax. Since INOMax is a gas, the dose is measured in parts per million, or ppm. If, for example, the INOMax dose is 20 ppm, there are 20 parts of nitric oxide in 1 million parts of the inhaled gas mixture.

Your doctor will decide how long you should be treated with INOMax®. Usually a baby being treated for hypoxic respiratory failure for 4 days or less, or until the condition improves. In patients who are having or just had, heart surgery and develop high blood pressure in the lungs, INOMax® is often given for 1 to 2 days, but sometimes treatment up to 7 days may be needed.

INOMax treatment should be stopped gradually, so that the circulation in the lungs is able to adjust to oxygen / air without INOMax. When your treatment with INOMax is almost finished, a gradual reduction in the amount of INOMax being administered will be supervised by your doctor. Abnormally low amounts of oxygen in the blood and slow heartbeat; low blood pressure and reduced amounts of blood being pumped out by the heart have been known to occur if treatment with INOMax is stopped suddenly without first lowering the dose.

Blood levels of substances called methaemoglobin, nitrogen dioxide and nitrate will be closely monitored by the doctor during treatment with INOMax.

## When to use INOMax

### *Near (>34 weeks) or term babies with hypoxic respiratory failure*

Usually a baby being treated for hypoxic respiratory failure is on INOMax therapy for 4 days or less, or until their condition improves.

### *Heart Surgery with high blood pressure in the lungs*

INOMax is often given for 1 to 2 days, but sometimes treatment up to 7 days may be needed.

## How INOMax is used

INOMax is a gas delivered to the lungs through a system designed for delivering nitric oxide.

## If you are given too much INOMax

As INOMax will be given under the supervision of your doctor it is unlikely that you will receive too much.

If you think that you have been given too much INOMax, you may need urgent medical attention.

### You should immediately:

phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using INOmax

### Things you should do

- Your doctor will give the lowest INOmax dose possible to try to avoid any side effects.
- The doctor will check for any side effects of the INOmax therapy and will decrease the INOmax dose or stop the INOmax therapy completely if necessary.

### Driving or using machines

You should not drive or operate machinery immediately following treatment.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

INOmax will be stored in the hospital pharmacy in a safe place out of the reach of children.

It should be stored below 25°C, avoid the temperature dropping to below 5°C.

INOmax should not be used after the expiry date on the box.

## 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Blood related:</b></p> <ul style="list-style-type: none"> <li>• Decreases the red blood cell capacity to carry oxygen.</li> </ul> <p><b>Lung related:</b></p> <ul style="list-style-type: none"> <li>• Lung injury</li> <li>• Chest discomfort</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>Your doctor will check your blood through regular testing</b></p>

### Serious side effects

The side effects in the following table may have potentially serious outcomes.

Serious side effects	What to do
<p><b>Blood related:</b></p> <ul style="list-style-type: none"> <li>• Reduced oxygen levels in the blood</li> </ul> <p><b>Broad or affecting different parts of the body:</b></p> <ul style="list-style-type: none"> <li>• infections</li> <li>• blood in the urine</li> <li>• high blood sugar</li> <li>• noisy breath sounds</li> <li>• low blood pressure</li> <li>• low blood potassium</li> <li>• airless or collapsed lungs</li> <li>• high amounts of bile pigment (bilirubin)</li> <li>• Increased blood clotting time</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://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 only available with a doctor's prescription.

### **What INOmax contains**

<b>Active ingredient (main ingredient)</b>	Nitric oxide
<b>Other ingredients (inactive ingredients)</b>	Nitrogen
<b>Potential allergens</b>	INOmax® does not contain: <ul style="list-style-type: none"><li>• Lactose</li><li>• Gluten</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What INOmax looks like**

INOmax is packaged in gas cylinders in the following concentrations:

- INOmax 800 ppm (AUST R 128136)
- INOmax 4,880 ppm (AUST R 513545)

Not all presentations may be marketed.

### **Who distributes INOmax®**

Ikaria Australia Pty Ltd  
Ground Floor, 17 Cotham Road,  
Kew, Victoria 3101  
Phone: (03) 9851 9100  
Website: [www.ikariaaust.com](http://www.ikariaaust.com)

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