

INOMax®

Nitric oxide medicinal gas for inhalation

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about INOMax®. It does not contain all the available information. It does not take the place of talking to your specialist, doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed up the risks of using INOMax® against the benefits it is expected to have for your baby or child.

If you have any questions about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What dosage form does INOMax® come in?

INOMax® is a therapeutic product that is in the form of a gas and is packaged in gas cylinders in a concentration of 800 parts per million (ppm).

What does INOMAX® contain?

Medicinal ingredient is:

Nitric oxide

Non-medicinal ingredients are:

Nitrogen is the only inactive ingredient. Nitrogen is a major component of the air we breathe.

What is INOMax® used for?

Babies who have been born near (>34 weeks) or at term and who have been diagnosed with a condition called hypoxic respiratory failure may be given INOMax®.

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.

INOMax® may also be given in babies and children (0 – 17 years old) 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 and improve heart function.

Before your baby's or child's doctor prescribes INOMax®, other types of therapy may be given to try to improve your baby's or child's condition. If these other therapies do not improve your baby's or child's 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.

How INOMax® works

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 your baby's or child's blood stream.

When INOMax® should not be used

INOMax® is not to be given to babies who are dependent on an abnormal circulation within the heart.

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

Passive exposure to INOMax® during pregnancy and breast-feeding should be avoided.

How to use INOMax®

Because side effects increase with higher doses of inhaled nitric oxide therapy, your baby or child 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.

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

Your baby's or child's doctor will decide the correct dose of INOMax® and will administer

INOMax® to your baby's or child's lungs through a system designed for delivering nitric oxide. This system delivers the correct amount of INOMax® to your baby's or child's lungs by diluting INOMax® with an oxygen/air mixture immediately before delivery.

For your baby's or child's safety, the delivery systems intended for administration of INOMax® are fitted with devices that constantly measure the amount of nitric oxide, nitrogen dioxide, and oxygen being delivered to your baby's or child's lungs. In addition, your baby's or child's blood will be tested throughout the treatment period to make sure there is no interference with the ability of the blood to carry oxygen.

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

INOMax® treatment should be stopped gradually, so that the circulation in your baby's or child's lungs is able to adjust to oxygen/air without INOMax®. When your baby's or child's treatment with INOMax® is almost finished, a gradual reduction in the amount of INOMax® being administered to your baby or child will be supervised by the doctor.

Abnormally low amounts of oxygen in the blood and slow heart beat; 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®.

If you take too much (overdose)

As INOMax® will be given to your baby or child under the supervision of your doctor it is unlikely that your baby or child will receive too much.

Before your baby or child is given INOMax®

Other things to be aware of before your baby or child is treated with INOMax® include:

Interactions with other medicines:

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

Medicines which may interact with INOMax® include nitroglycerine, sodium nitroprusside, vasodilators such as sildenafil, surfactants, prilocaine, alkyl nitrates and sulphonamides. Your doctor or pharmacist will assess any potential interactions with any other medicines before INOMax® treatment is commenced.

Patients with 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, 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® against the benefits it is expected to provide.

Side effects

Like all medicines, nitric oxide can have side effects. Your baby's or child's doctor will examine your baby or child closely for all side effects. If you notice any side effects not mentioned in this leaflet, even after your baby or child leaves the hospital, please inform the doctor.

Short-term 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 your baby's or child's lungs. The doctor should be monitoring the blood for these and other effects.

If your baby or child has these side effects, the longterm clinical outcomes are unknown.

When your baby or child is receiving INOMax® therapy the INOMax® cannot be stopped too quickly. The dose of INOMax® will be gradually reduced because oxygen levels in your child's blood may get worse when INOMax® is stopped too quickly.

Other side effects of inhaled nitric oxide may include: infections, blood in the urine, high blood sugar, noisy breath sounds, low blood platelets, low blood pressure, low blood potassium, airless or collapsed lungs and high amounts of bile pigment (bilirubin).

Nitric oxide gas may in some cases cause blood not to clot as well as usual.

Accidental exposure of hospital staff to INOMax® has been associated with chest discomfort, dizziness, dry throat, headache and shortness of breath.

Long-term side effects

Studies of inhaled nitric oxide in newborn babies have not followed the babies' condition for more than 2 years, so long-term side effect information is not definitely known.

If your baby or child receives INOMax® therapy, it is

recommended that you have your baby or child checked by a doctor periodically and monitored for normal developmental signs, including: growth, vision, hearing, physical development, lung development, and learning development.

Controlling side effects

Your baby's or child's doctor will give the lowest INOmax® dose possible to try to avoid any side effects. Your baby's or child's 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.

This is not a complete list of side effects. For any unexpected effects while your baby or child is taking INOmax® contact your doctor.

Product description

Ingredients

Each cylinder of INOmax® contains the active ingredient Nitric oxide 800 ppm.

INOmax® also contains: Nitrogen, Grade 5

INOmax® is supplied as

- a size MD 15 cylinder
- a size 88 cylinder

INOmax® does not contain:

- lactose
- gluten
- preservative

Storage

Store at 25°C, avoid temperature dropping to below 5°C.

Keep INOmax® out of the reach of children.

Note the expiry date on the pack.

Do not use after this expiry date.

Sponsor

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Where to go for further information

Ikaria is not in a position to give people an individual diagnosis or medical advice. Your doctor, nurse or pharmacist is the best person to give you advice on the treatment of your baby's or child's condition. You may also be able to find general information about your baby's or child's condition and its treatment from patient support groups.

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