

CONSUMER INFORMATION
Product Monograph Part III

INOmax[®]
nitric oxide for inhalation
100 ppm, 800 ppm, gas

INO Therapeutics

Submission Control No. 085333

The Consumer Information Section (Part III) of the Product Monograph for INO max has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on September 23, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

INOMax^a

nitric oxide for inhalation

This leaflet is part III of a three-part "Product Monograph" published when INOMax was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INOMax. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Babies who have been born near 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 (fecal material that blocks the lungs) and infection, may cause hypoxic respiratory failure.

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

What it does:

INOMax can improve the flow of blood through the lungs by relaxing the cells in the blood vessels and allowing the blood vessels to widen. This may help to increase the amount of oxygen that reaches your baby's blood.

When it should not be used:

INOMax is not to be given to babies who have an abnormal circulation within the heart.

Some babies may have hypoxic respiratory failure, but may not be helped by INOMax. If the hypoxic respiratory failure is caused by a condition known as congenital diaphragmatic hernia (when the bowel moves into the lung area), INOMax has not been shown to be effective.

INOMax should not be used in pre-mature babies born before 34 weeks from conception.

What the medicinal ingredient is:

nitric oxide

What the important nonmedicinal ingredients are:

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

What dosage forms it comes in:

INOMax is a drug product that is in the form of a gas and is packaged in gas cylinders in concentrations of 800 and 100 parts per million (ppm).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Your baby's doctor will examine your baby for all side effects, including:

- \$a decrease in the ability of the blood to carry oxygen
- \$an increase in the amount of inhaled nitrogen dioxide
- \$a worsened condition if INOMax therapy is stopped too quickly

INOMax is not indicated for use in the adult population. Passive exposure to INOMax during pregnancy and breast-feeding should be avoided.

INTERACTIONS WITH THIS MEDICATION

The doctor will decide when to treat your baby with INOMax and with other medicines, and will carefully supervise the treatment. INOMax could be given with some medicines called "nitric oxide donors" or drugs that themselves can affect the blood's ability to carry oxygen.

PROPER USE OF THIS MEDICATION

Because side effects increase with higher doses of inhaled nitric oxide therapy, your baby 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 baby's doctor will decide the correct dose of INOMax and will administer INOMax to your baby's lungs through a system designed for delivering nitric oxide. This system delivers the correct amount of INOMax to your baby's lungs by diluting INOMax with an oxygen/air mixture immediately before delivery.

For your baby'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 lungs. In addition, your baby'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 doctor will decide how long your baby should be treated with INOMax. Usually a baby is on INOMax therapy for 4 days or less.

INOMax treatment should be stopped gradually, so that the circulation in your baby's lungs is able to adjust to oxygen/air without INOMax. So when your baby's treatment with INOMax is almost finished, a gradual reduction in the amount of INOMax being administered to your baby will be supervised by your baby's doctor. Low blood pressure has been known to occur if treatment with INOMax is stopped suddenly without first lowering the dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, nitric oxide can have side effects. Your baby's doctor will examine your baby closely for all side effects. If you notice any side effects not mentioned in this leaflet, even after your baby leaves the hospital, please inform your baby's 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 lungs. The doctor should be monitoring the blood for these and other effects.

If your baby has these side effects, the long-term clinical outcomes are unknown.

When your baby 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: low blood pressure, blood in urine, high blood sugar, blood poisoning, infection, and skin infection.

Nitric oxide gas may in some cases cause blood not to clot as well and cause bleeding in the brain or lungs.

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. There are possibly long-term side effects that could affect the development of the lungs, brain and walking ability.

If your baby receives INOmax therapy, it is recommended that you have your baby checked by a doctor periodically and monitored for normal developmental signs, including: growth, hearing, physical development, lung development, and learning development.

In order to find out more information about the long-term effects of INOmax therapy given to newborn babies, the company that manufactures INOmax has committed to Health Canada to collect additional safety information. This safety information will be collected on children at several stages in their development and will continue until they are at least 5-years old.

Controlling side effects

Your baby's doctor will give the lowest INOmax dose possible to try to avoid any side effects. Your baby'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 taking INOmax, contact your doctor.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadtmp@hc-sc.gc.ca

By regular mail:

National AR Centre

**Marketed Health Products Safety and Effectiveness
Information Division**

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, INO Therapeutics, at:

1-877-KNOWINO

This leaflet was prepared by INO Therapeutics

Last revised: September 19, 2005