What is INOmax?
INOmax (also known as inhaled nitric oxide) is an inhaled drug that is approved by the U.S. Food and Drug Administration (FDA) for treating Hypoxic Respiratory Failure (HRF) in newborns greater than 34 weeks fetal age (age from conception). HRF means that your newborn isn’t getting enough oxygen into his or her blood. Newborns with this form of breathing failure are unable to breathe on their own and have high pressure in the blood vessels of their lungs. High pressure in the blood vessels of the lungs is known as pulmonary hypertension.

What is the most important information to know about INOmax?
Your baby will receive this medication in a neonatal intensive care unit (NICU) or similar hospital setting.
INOmax is inhaled through the mouth or nose into your baby’s lungs. Your baby may also be using a breathing tube connected to a ventilator (a machine that moves air in and out of the lungs to help your baby breathe and get enough oxygen).
Your baby should remain under supervision during treatment with nitric oxide.

Who should not use INOmax?
Normally blood will flow from the left side to right side of the heart. INOmax must not be used in newborns that solely depend on blood that flows from right side to the left side of the heart.
INOmax is not used in adults.

What should I tell my baby’s healthcare provider before taking INOmax?
Tell your healthcare provider about all other medical conditions and any other medications being taken by your baby, including any ointments being applied to your baby’s skin.

How does INOmax work?
Your baby will be given INOmax when the tiny blood vessels surrounding the small air sacs in the lungs (called alveoli) are too narrow. The narrow blood vessels limit the amount of blood flowing through the lungs and then limit the amount of oxygen being taken from the lungs into the body.

When INOmax is given to your newborn, it may be mixed with oxygen and will relax the tiny, narrow blood vessels surrounding the small air sacs in the lungs. As the vessels relax, blood flow through these vessels improves. This allows more oxygen to move from the lungs to the blood and may improve oxygen levels in the newborn’s blood.
INOmax is given to your baby through a machine called the INOmax DSIR®, which works with the oxygen delivery system.

What should be avoided while taking INOmax?
INOmax should not be stopped suddenly. The healthcare provider will decrease the dose in several steps, pausing at each step to gradually stop INOmax treatment.

What are the possible side effects of INOmax?
INOmax may cause the following serious side effects:
• Worsening oxygen levels in the blood if the medicine is suddenly stopped
• Reduced ability for blood to carry oxygen
• Injury to lungs
• Heart failure
INOmax may also cause a decrease in blood pressure.
These are not all the possible side effects of INOmax. For more information on these and other side effects associated with INOmax, talk to your healthcare provider, visit our website at www.inomax.com, or call 877-566-9466.

You may report negative side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Need more information?
• Ask your doctor or pharmacist.
• Go to www.inomax.com or call 877-566-9466.

This brief summary is based on INOmax Prescribing Information, revised October 2015.
How Do Babies Breathe Before Birth?

- Before babies are born, they get oxygen from the **placenta** through the **umbilical cord**.
- The placenta does all the work so the **lungs** are not needed for breathing.
- Increased pressure in the lungs moves blood away from the lungs through openings called the **foramen ovale** and **ductus arteriosus**.
- The foramen ovale is an opening between the upper-right side and the upper-left side of the heart.
- The ductus arteriosus is an opening between the aorta and pulmonary artery.

How Do Babies Breathe After Birth?

- After babies are born, the umbilical cord is cut and they no longer receive oxygen from the placenta (mother).
- With the first breaths, the lungs inflate to breathe in oxygen from the air.
- Decreased pressure in the lungs allows blood to flow from the heart into the lungs, and the foramen ovale and ductus arteriosus begin to close.
- Oxygenated blood is then pumped by the heart to the rest of the body.
Why Is My Baby Having Trouble Breathing?

- When some babies are born, they do not adapt to breathing on their own
- Increased pressure in their lungs continues to move blood away from the lungs, back through the foramen ovale and ductus arteriosus openings in the heart
- Oxygen that is breathed into the lungs is not picked up by the blood or carried to the organs to support the body
- This can result in a condition called hypoxic respiratory failure, also known as HRF, where the cells in the body do not receive enough oxygen

What Causes HRF?

HRF can be caused by many things, including:

- Persistent Pulmonary Hypertension of the Newborn (PPHN): increased pressure in the blood vessels of the lungs moves blood away from the lungs. Oxygen that is breathed into the lungs is not picked up by the blood and carried to the rest of the body
- Respiratory Distress Syndrome (RDS): the lungs don’t make enough surfactant, a substance that helps keep the alveoli open so the lungs can expand and breathe in oxygen
- Meconium Aspiration Syndrome (MAS): a baby breathes in (aspirates) a mixture of amniotic fluid and meconium (stool) that can block the airway and make it difficult to breathe
- Pneumonia: an infection in the lungs that causes inflammation that blocks the alveoli, preventing oxygen from getting into the blood
- Sepsis: a blood infection that can spread to other parts of the body, including the lungs

See back cover for important information about inhaled nitric oxide.
Healthy Heart & Lungs
See back cover for important information about inhaled nitric oxide.
How Is HRF Diagnosed?

There are several tests that can help determine if a baby has HRF. These may include:

- **Blood Test/Blood Gas**: measures how much oxygen is in the blood
- **Echocardiogram**: sound waves produce a moving picture of the heart to see the structures of the heart, how it is beating and pumping blood, and any signs of heart disease
- **Pulse Oximetry (Pulse Ox)**: sensors placed on the hand and foot measure oxygen levels and determine if there is enough oxygen in the blood
- **Chest X-Ray**: determines if there is a problem with the lungs and/or heart

How Is HRF Treated?

The goal of treatment is to increase oxygen levels in the blood. Treatment will depend on the cause of HRF and how a baby is doing. Treatment may include:

- **Oxygen**: an inhaled treatment given to babies to increase oxygen levels in the blood
- **Surfactant**: a medicine used to replace natural surfactant that helps keep the alveoli open so the lungs expand and breathe in oxygen
- **Antibiotics**: medicines used to help fight infection
- **Sedation**: medicines given to help calm a baby and reduce a baby’s use of oxygen
- **Inhaled Nitric Oxide**: an inhaled medicine given as a gas to relax and open blood vessels surrounding the lungs
- **Respiratory Support**:
  - **Mechanical Ventilation**: a machine that helps people breathe by blowing air or a mixture of gases (oxygen and air) into the lungs through an endotracheal tube
  - **Continuous Positive Airway Pressure (CPAP)**: a device that blows a gentle stream of air or a mixture of gases (oxygen and air) to keep the airway open and reduce the work of breathing
  - **Nasal Cannula**: a device that delivers air or a mixture of gases (oxygen and air) by way of 2 small tubes that are inserted into the nose
What Is Inhaled Nitric Oxide?

- Inhaled nitric oxide is a medicine given as a gas that helps increase oxygen levels in the blood when a baby does not have enough oxygen.
- Inhaled nitric oxide is approved by the FDA to treat babies with HRF associated with pulmonary hypertension.

How Does Inhaled Nitric Oxide Work?

- Inhaled nitric oxide is delivered directly to the lungs, where it causes blood vessels to relax and open.
- As the blood vessels open, pressure in the lungs decreases, allowing increased blood flow to the lungs.
- Oxygen that is breathed into the lungs is picked up by the blood and pumped to the rest of the body by the heart.
- Inhaled nitric oxide may not work for all babies, and other types of treatment may be necessary.

See back cover for important information about inhaled nitric oxide.
Inhaled nitric oxide delivery device

Respiratory Support
- Mechanical Ventilation
- Continuous Positive Airway Pressure (CPAP)
- Nasal Cannula

Endotracheal tube
What Can I Expect With Treatment of Inhaled Nitric Oxide?

Many babies respond well to treatment for HRF. Each baby is different. Talk with your neonatal intensive care unit (NICU) team about your baby’s treatment options.

- Inhaled nitric oxide may be given with other types of treatments
- Inhaled nitric oxide may help increase oxygen levels in a baby’s blood and reduce the need for more invasive treatments
- The baby will be slowly weaned from the ventilator and treatment with inhaled nitric oxide
- A baby’s breathing will be monitored closely to make sure that enough oxygen is getting into the blood
- If inhaled nitric oxide does not work, a baby may be given another type of treatment to help increase oxygen levels in the blood
- Inhaled nitric oxide may cause serious side effects, including worsening oxygen levels in the blood if the medicine is suddenly stopped, reduced ability for blood to carry oxygen, injury to lungs, heart failure, and a decrease in blood pressure
- These are not all of the side effects of inhaled nitric oxide. You should talk to your healthcare provider about these and other side effects associated with the use of inhaled nitric oxide

What Questions Should I Ask My Baby’s NICU Team?

- What is my baby’s diagnosis?
- What will be involved in my baby’s treatment and care?
- What medicines will my baby have to take?
- What type of tests will have to be done?
- How will I know if my baby is getting better?
- What can I do to help my baby?
- Can I stay with my baby?
- Will I be able to hold or touch my baby?
- How will I know when my baby is ready to go home?
- What sort of care will my baby need when we get home?
- When will my baby be able to feed?
Airway: a passage where air travels from the nose or mouth to the lungs
Amniotic fluid: the fluid inside the womb in which a baby floats before birth
Aspirate: fluid or foreign matter is breathed into the airway
Continuous positive airway pressure (CPAP): a device that blows a gentle stream of air or mixture of gases (oxygen and air) to keep the airway open and reduce the work of breathing
Ductus arteriosus: a blood vessel that connects the aorta to the pulmonary artery (bypassing the lungs) that normally closes soon after birth
Endotracheal tube: a tube that goes through the mouth or nose into the airway to deliver air or a mixture of gases (like oxygen and air) to the lungs
Foramen ovale: an opening between the upper-right side and upper-left side of the heart that usually closes soon after birth
Hypoxic respiratory failure (HRF): a condition where the cells in the body do not receive enough oxygen
Inflammation: a reaction of tissue to injury or infection, characterized by pain, redness, and swelling
Lungs: organs in the chest that allow the body to take in oxygen from the air
Mechanical ventilation: a machine that helps people breathe by blowing air or a mixture of gases (oxygen and air) into the lungs through an endotracheal tube
Meconium: the first feces (stool) passed by a baby
Nasal cannula: a device that delivers air or a mixture of gases (oxygen and air) by way of 2 small tubes that are inserted into the nose
Placenta: an organ that develops and attaches to the wall of the uterus during pregnancy to provide oxygen and nutrients to a growing baby
Pulmonary hypertension: increased pressure in the blood vessels of the lungs moves blood away from the lungs
Surfactant: a substance that helps keep the alveoli open so the lungs can expand and breathe in oxygen
Umbilical cord: connects a developing baby to the placenta; supplies oxygen-rich blood to an unborn baby and removes wastes
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Important Facts about INOmax®

Read this patient information before your baby takes INOmax; there may be new information. If you have questions, ask your healthcare provider.

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Who should not use INOmax?
During this time, it is unknown whether INOmax is excreted in breast milk. Therefore, breastfeeding may not be advised. In addition, INOmax will be given only if the potential benefit justifies the potential risk to the nursing infant. It is not known if INOmax is excreted in human milk or if it can harm the nursing baby.

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You may report negative side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Need more information?
- Ask your doctor or pharmacist.

This is only a summary of important information.
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