

# About INOMAX<sup>®</sup> (nitric oxide) for inhalation

*INOMAX<sup>®</sup> is the only naturally occurring signalling molecule in gas form that is FDA approved to treat newborn infants with hypoxic respiratory failure (HRF),<sup>1,2</sup> a potentially fatal condition in which newborns are unable to transport enough oxygen from the air that they breathe.<sup>3</sup>*

## Indication

INOMAX, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension,<sup>4,5</sup> where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

## Product Information

Nitric oxide (NO), the active substance in INOMAX, is a naturally occurring compound produced by many cells in the human body.<sup>6</sup> NO is known as a "signalling molecule" because it is able to penetrate cell walls to deliver a biochemical signal.<sup>7</sup> When NO enters cells in the walls of a blood vessel in the lungs, it sends a signal that causes nearby muscles to relax. This process is known as pulmonary vasodilation.<sup>8</sup>

As the muscles of the blood vessel relax, blood flow increases, helping the heart and lungs to process more oxygen and deliver more oxygenated blood into a baby's bloodstream. The researchers who discovered the signaling capabilities of NO in the human body earned the *Nobel Prize for Physiology and Medicine*.<sup>9</sup>

By rapidly improving oxygenation, INOMAX may help reduce the amount of time patients require mechanical ventilation and respiratory support. Treatment with INOMAX reduces the need for extracorporeal membrane oxygenation, a highly invasive form of surgery that requires the use of a heart-lung machine.<sup>10</sup>

INOMAX is the drug component of INOtherapy<sup>®</sup>, a comprehensive suite of services and technologies that includes: the INOvent<sup>®</sup> and INOMAX<sup>®</sup> DS drug-delivery technologies; 24/7/365 customer service; emergency deliveries; medical and technical support; on-site training; regular monitoring and upgrades; and business support.

INOMAX was approved in 1999 by the US Food & Drug Administration, and is approved for use in Europe, Australia, Mexico, and in Japan, where it is marketed as INOflo<sup>®</sup>. INOMAX, INOflo, INOMAX DS and INOtherapy are developed, designed, manufactured and distributed by Ikaria.

## Administration and Dosing

The recommended dose of INOMAX is 20 parts per million (ppm), which should be maintained for up to 14 days or until the underlying oxygen desaturation has resolved.<sup>11</sup> INOMAX should not be discontinued abruptly. INOMAX is administered via inhalation using the INOvent, a specialized, bedside unit or through the smaller, transportable INOMAX DS system.

## Safety

INOMAX should not be used in the treatment of infants known to be dependent on right-to-left shunting of blood. Sudden discontinuation of INOMAX may lead to a worsening condition. Methemoglobinemia is a dose-dependent side effect of inhaled nitric oxide therapy. Nitrogen dioxide (NO<sub>2</sub>) forms rapidly in gas mixtures containing nitric oxide and oxygen and may cause airway inflammation and damage. Methemoglobin, NO<sub>2</sub>, and FiO<sub>2</sub> should be monitored during nitric oxide administration.<sup>12</sup>

Warning: The INOvent and INOmax DS Delivery Systems must only be used in accordance with the indications, usage, contraindications, warnings and precautions described in the nitric oxide drug package inserts and labeling.

For more information on INOmax and its delivery devices, including important safety information and full prescribing information, please visit [www.inomax.com](http://www.inomax.com).

### References:

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