

Important Safety Information

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

The safety and effectiveness of inhaled nitric oxide have been established in a population receiving other therapies for hypoxic respiratory failure, including vasodilators, intravenous fluids, bicarbonate therapy, and mechanical ventilation.

- INOMAX should not be used in the treatment of neonates known to be dependent on right-to-left shunting of blood
- Methemoglobinemia is a dose-dependent side effect of inhaled nitric oxide therapy. Therefore, methemoglobin levels should be monitored during INOMAX administration. Caution should be used when administering INOMAX with other drugs that can cause methemoglobinemia regardless of their route of administration
- Nitrogen dioxide (NO₂) rapidly forms in gas mixtures containing nitric oxide and oxygen. NO₂ formed in this way can cause airway inflammation and damage
- INOMAX must be administered through a system that does not cause excessive generation of NO₂ and that monitors for NO, NO₂, and FiO₂
- Abrupt discontinuation of INOMAX therapy can lead to worsening of PaO₂ and increasing pulmonary artery pressure (PAP). Deterioration in oxygenation and elevation in PAP can also occur in children with no apparent response to INOMAX
- In patients with pre-existing left ventricular dysfunction, inhaled nitric oxide may increase pulmonary capillary wedge pressure leading to pulmonary edema