**Indication**

*Noxivent* is a vasodilator indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

**Important Safety Information**

**Contraindications**

*Noxivent* is contraindicated in neonates dependent on right-to-left shunting of blood.

**Warnings and Precautions**

**Rebound:** Abrupt discontinuation of *Noxivent* may lead to worsening oxygenation and increasing pulmonary artery pressure.

**Methemoglobinemia:** Methemoglobin levels increase with the dose of *Noxivent*; it can take 8 hours or more before steady-state methemoglobin levels are attained. If methemoglobin levels do not resolve with decrease in dose or discontinuation of Noxivent, additional therapy may be warranted to treat methemoglobinemia.

**Airway injury from Nitrogen Dioxide:** Monitor nitrogen dioxide (NO₂) levels. Nitrogen dioxide may cause airway inflammation and damage to lung tissue.

**Heart Failure:** In patients with pre-existing left ventricular dysfunction, *Noxivent* may increase pulmonary capillary wedge pressure leading to pulmonary edema.

**Adverse Reactions**

The most common adverse reaction of *Noxivent* is hypotension.

**Drug Interactions**

Nitric Oxide donor compounds may increase the risk of developing methemoglobinemia.

**Administration**

Use only with a calibrated NOxBOX® delivery system operated by trained personnel. Only validated ventilator systems should be used in conjunction with *Noxivent*.

Please see the full Prescribing Information for additional important *Noxivent* safety and risk information.

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