

## PART III: CONSUMER INFORMATION

### <sup>Pr</sup>Noxivent™ nitric oxide for inhalation 100 ppm and 800 ppm Medical Gas

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

## ABOUT THIS MEDICATION

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Babies who have been born at term or late pre-term and who have been diagnosed with a condition called hypoxic respiratory failure may be given *Noxivent*™.

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 *Noxivent*™, 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, *Noxivent*™ may be given.

#### What it does:

*Noxivent*™ 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:

*Noxivent*™ 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 *Noxivent*™. If the hypoxic respiratory failure is caused by a condition known as congenital diaphragmatic hernia (when the bowel moves into the lung area), *Noxivent*™ has not been shown to be effective.

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

#### What the medicinal ingredient is:

nitric oxide

#### What the nonmedicinal ingredients are:

Nitrogen

#### What dosage forms it comes in:

*Noxivent*™ 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 *Noxivent*™ therapy is stopped too quickly

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

## INTERACTIONS WITH THIS MEDICATION

The doctor will decide when to treat your baby with *Noxivent*™ and with other medicines, and will carefully supervise the treatment. *Noxivent*™ 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 *Noxivent*™. Since *Noxivent*™ is a gas, the dose is measured in parts per million, or ppm. If for example the nitric oxide 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 *Noxivent*™ and will administer *Noxivent*™ to your baby's lungs through a system designed for delivering nitric oxide. This system delivers the correct amount of *Noxivent*™ to your baby's lungs by diluting *Noxivent*™ with an oxygen/air mixture immediately before delivery.

For your baby's safety, the delivery systems intended for administration of *Noxivent*™ 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 *Noxivent*™. Usually a baby is on *Noxivent*™ therapy for 4 days or less.

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

### Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

## SIDE EFFECTS AND WHAT 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.

In some babies with heart failure, inhaled nitric oxide may cause a worsening of the blood circulation in the heart and lungs.

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

When your baby is receiving *Noxivent*<sup>TM</sup> therapy the *Noxivent*<sup>TM</sup> cannot be stopped too quickly. The dose of *Noxivent*<sup>TM</sup> will be gradually reduced because oxygen levels in your child's blood may get worse when *Noxivent*<sup>TM</sup> 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 *Noxivent*<sup>TM</sup> 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 nitric oxide therapy given to newborn babies, the company that manufactures nitric oxide 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 *Noxivent*<sup>TM</sup> dose possible to try to avoid any side effects. Your baby's doctor will check for any side effects of the *Noxivent*<sup>TM</sup> therapy and will decrease the *Noxivent*<sup>TM</sup> dose or stop the *Noxivent*<sup>TM</sup> therapy completely if necessary.

***This is not a complete list of side effects. For any unexpected effects while taking Noxivent<sup>TM</sup>, contact your doctor.***

### Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### 3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
  - By calling 1-866-234-2345 (toll-free);
  - By completing a Consumer Side Effect Reporting Form and sending it by:
    - Fax to 1-866-678-6789 (toll-free), or
    - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

***NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.***

## MORE INFORMATION

### Storage

*Noxivent*<sup>™</sup> cylinders are stored at controlled room temperature 15-30 °C.

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Praxair Canada Inc., at:

**1-800-PRAXAIR (800-772-9247)**

This leaflet was prepared by Praxair Canada Inc.

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