

09.06.2025

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לצרכן של התכשיר הבא:

### **Mixture 800 ppm NO in Nitrogen**

התכשיר מיועד להתוויה:

Mixture 800 ppm NO in Nitrogen, in conjunction with ventilatory support and other appropriate active substances, is indicated:

- for the treatment of newborn infants  $\geq 34$  weeks gestation with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, in order to improve oxygenation and to reduce the need for extracorporeal membrane oxygenation.
- As part of the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function and oxygenation.

**השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:**

#### **4.4 Special warnings and precautions for use**

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##### **Pulmonary veno-occlusive disease**

Cases of life-threatening pulmonary oedema have been reported with nitric oxide in patients with pulmonary veno-occlusive disease. Therefore, the possibility of a veno-occlusive disease should be carefully evaluated if signs of pulmonary oedema occur following the administration of nitric oxide to patients with pulmonary hypertension. If confirmed, the treatment is to be discontinued.

בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו.

בברכה,

Mini Hazan  
Appointed Pharmacist  
מירי חזן  
License No. 7124

מירי חזן

רוקחת ממונה