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EPAR summary for the public

INOmax

nitric oxide

This is a summary of the European public assessment report (EPAR) for INOmax. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for INOmax.

What is INOmax?

INOmax is a gas for inhalation that contains the active substance nitric oxide diluted in nitrogen gas at 400 or 800 parts per million (ppm).

What is INOmax used for?

INOmax is used in combination with artificial ventilation and other medicines to help improve blood oxygen levels in the following groups of patients:

- newborn babies (born after 34 weeks of gestation) with breathing problems associated with pulmonary hypertension (high blood pressure in the lungs). INOmax is used in these babies to improve oxygen supply levels and to reduce the need for extracorporeal membrane oxygenation (ECMO, a technique to oxygenate the blood outside the body using a device similar to a heart-lung machine).
- patients of all ages who are undergoing or have undergone heart surgery and develop pulmonary hypertension. In these patients INOmax is used to help improve heart function and reduce blood pressure in the lungs.

The medicine can only be obtained with a prescription.



How is INOmax used?

INOmax treatment should be supervised by a doctor who has experience in intensive care or neonatal intensive care if the patient is a newborn baby. INOmax should only be used in units where staff have been trained in the use of a nitric oxide delivery system.

INOmax is used in patients who are undergoing artificial ventilation, once the ventilation is optimised. INOmax is given after being diluted in an oxygen/air mixture supplied to the patient through the ventilator.

The maximum starting dose of INOmax is 20 ppm for children up to 18 years of age, and 40 ppm for adults. This should then be reduced to 5 ppm, provided the blood in the arteries contains enough oxygen. In newborn babies with breathing problems, treatment can be continued at this dose until there is improvement in oxygen levels, for a maximum of four days. In children and adults undergoing heart surgery, treatment usually lasts for 24 to 48 hours. Treatment should not be stopped abruptly. For more information, see the summary of product characteristics.

How does INOmax work?

The active substance in INOmax, nitric oxide, is a naturally-occurring chemical in the body, which causes the muscles in the lining of the blood vessels to relax. When inhaled, it causes the vessels in the lungs to dilate (widen); this allows blood to flow more easily in the lungs to supply oxygen to the rest of the body and remove carbon dioxide, reducing pulmonary hypertension. It also helps to decrease inflammation in the lungs.

How has INOmax been studied?

Because nitric oxide is a well-known chemical, the company used data from the published literature to support INOmax's use in newborn babies with pulmonary hypertension, and in adults and children undergoing heart surgery.

INOmax has also been studied in 421 neonates from 34 weeks gestation with pulmonary hypertension in two main studies. In the first study, 235 neonates with respiratory failure received either INOmax or placebo (a dummy treatment). The main measure of effectiveness was the proportion of neonates who died or needed ECMO over the first 120 days in hospital. In the second study, 186 neonates with respiratory failure received either INOmax or placebo. The main measure of effectiveness was the proportion of neonates who needed ECMO.

What benefit has INOmax shown during the studies?

In the two main studies in newborn babies with breathing problems, INOmax was more effective than placebo at reducing the need of ECMO. In the first main study, 52 (46%) of the 114 neonates receiving INOmax died or needed ECMO, compared with 77 (64%) of the 121 receiving placebo. This was mainly due to a reduction in the need for ECMO, rather than a reduction in death rates. In the second main study, 30 (31%) of the neonates receiving INOmax needed ECMO, compared with 51 (57%) of the 89 receiving placebo.

In the published literature, INOmax treatment was shown to reduce the blood pressure in the lungs and improve heart function when used during or after heart surgery.

What is the risk associated with INOmax?

The most common side effect with INOmax (seen in more than 1 patient in 10) are thrombocytopenia (low blood platelet counts), hypokalaemia (low blood potassium levels), hypotension (low blood pressure), atelectasis (collapse of the whole, or part of a, lung), and hyperbilirubinaemia (high blood levels of bilirubin). For the full list of all side effects reported with INOmax, see the package leaflet.

INOmax should not be used in babies who may be hypersensitive (allergic) to nitric oxide or the other ingredient (nitrogen). It must not be used in babies who have right-to-left or significant left-to-right shunting of blood (abnormal circulation of blood in the heart).

What measures are being taken to ensure the safe use of INOmax?

The company must put in place an educational programme to ensure that doctors who are going to use INOmax for the treatment of patients undergoing heart surgery are aware of the risks and the precautions necessary when using the medicine.

Why has INOmax been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that INOmax's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about INOmax

The European Commission granted a marketing authorisation valid throughout the European Union for INOmax on 1 August 2001. The marketing authorisation holder is Linde Healthcare AB. The marketing authorisation is valid for an unlimited period.

The full EPAR for INOmax can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). For more information about treatment with INOmax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist..

This summary was last updated in 12-2012.