INOMAX DS Drug-Delivery System: Class I Recall - Risk of Interruption of Drug Flow

U.S. Food & Drug Administration

AUDIENCE: Pulmonology, Risk Manager

ISSUE: Ikaria, Inc. notified healthcare professionals of a Class I Recall of the INOMAX (nitric oxide) Drug-Delivery System. There is a potential for failure of a pressure switch which may have an impact on the administration of INOMAX for inhalation to patients. Risks to the patient may include interruption of drug flow due to an empty cylinder, and/or the time taken to switch to a replacement system. An interruption or delay in the administration of INOMAX therapy may cause:

- Worsening of low blood oxygen level (hypoxemia)
- Low blood pressure (hypotension) and/or
- Increase in blood pressure in the pulmonary arteries (pulmonary hypertension)
- Death

BACKGROUND: INOMAX is a vasodilator, which, in conjunction with ventilator support and other appropriate agents, is indicated for the treatment of term and near-term (> 34 weeks gestation) neonates with hypoxic respiratory failure.

RECOMMENDATION: If a leak is suspected, clinicians should: 1) not interrupt the delivery of INOMAX; 2) verify an adequate amount of INOMAX remains in the cylinder; 3) switch to the manual back-up system using the INOblender by connecting the INOMAX Inlet Hose of the INOblender directly to the INOMAX regulator, and follow the standard procedure for use of the INOblender as the primary back-up method for manual ventilation, and; 4) contact Ikaria Customer Care at 1-877-KNOW-INO (1-877-566-9466) for assistance. Although the risk of INOMAX exposure to pregnant women is unknown, it is advised that healthcare professionals who may be pregnant avoid the immediate area in which a leak is suspected.

[08/23/2010 - Recall Notice [1] - FDA]
[08/11/2010 - Press Release [2] - Ikaria, Inc]

SOURCE [3]

Source URL (retrieved on *07/22/2014 - 9:41pm*):

http://www.mdtmag.com/news/2010/08/inomax-ds-drug-delivery-system-class-i-recall-risk-interruption-drug-flow

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm223667.htm
[2] http://www.fda.gov/Safety/Recalls/ucm221940.htm
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm223746.htm