

Linde Healthcare AB
Agavägen 54
18181 Lidingö
Sweden
Lidingö, dth Month 2017

INOMax (nitric oxide) cylinders: Gas delivery might stop in the month of expiry when used with the Device INOMax DSIR

Dear Healthcare professional,

Linde Healthcare AB in agreement with <the European Medicines Agency> and the MHRA would like to inform you of the following:

Summary

- A defect is affecting INOMax (nitric oxide) gas cylinders, which means that any cylinders that are close to their expiry date and used with the INOMax DSIR nitric oxide delivery device (DSIR) will not work. Any INOMax cylinders that are due to expire within the next 3 months should therefore be replaced through the company's replacement programme.
- Any treatment that is started prior to the beginning of the month of expiry will continue during the month of expiry. However, if treatment is interrupted, a restart during the month of expiry with the INOMax DSIR device will not be possible. If this happens without weaning the patient, it could lead to a potentially life-threatening rebound effect.
- In order to minimise the risk of adverse reactions caused by stopping gas delivery, Linde runs a replacement program to ensure that all INOMax cylinders are removed 3 months before the month of expiry. A list of cylinders that expire in the next 3 months will be sent by post or email to you regularly to facilitate the replacement programme.
- The defect applies to 400 ppm and 800 ppm cylinders of both 2L and 10L pack sizes, but only when used with the INOMax DSIR device.

Further information on the safety concern and the recommendations

In March 2017 a defect was found with INOmax (nitric oxide) gas cylinders, which means that any cylinders that are close to their expiry date and used with the INOmax DSIR nitric oxide delivery device (DSIR) will not work. The defect means that the device can no longer read the expiry date correctly. Instead of reading the expiry date as the last day of the month the device reads the expiry as the first day of the month. If INOmax is started at any time during the month of expiry, the device will alarm and the delivery of nitric oxide will stop after 2 minutes.

In case treatment has already been started and the therapy gets interrupted the back-up systems of the INOmax DSIR should be used until you have connected a new cylinder on the device with an expiry date accepted by the device.

The pneumatic primary back-up device INOblender (part of the INOmax DSIR device) can always be activated in case the INOmax DSIR stops delivery.

Further information

Please contact your local distributor in the event that you are in possession of expired cylinders and/or cylinders within the last 3 months prior to the labelled expiry month, and have not been contacted about their replacement.

Linde's local distributor will contact you to clarify details relating to the exchange.

Call for reporting

Please continue to report any suspected defective INOmax cylinders to <insert details of national reporting system>.

Company contact point

If you want further information relating to the above, please contact _____.

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