Nostrum Expands Voluntary Nationwide Recall of Metformin HCl Extended Release Tablets, USP 750 mg, Due to NDMA Content

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Nostrum Laboratories has posted a recall of 1 lot of metformin hydrochloride (HCl) extended release (ER) tablets in the strength of 750 mg.

About this Recall:
Nostrum is voluntarily recalling one (1) lot of metformin HCl ER tablets in the strength of 750 mg to the consumer level. This product is the generic equivalent to Glucophage® tablets. The recalled metformin HCl ER 750 mg tablets have been found to contain levels of nitrosamine impurities above the acceptable daily intake limit of 96 ng/day. This is an expansion of the recall initially announced on November 2, 2020.

What this means to you:
N-Nitrosodimethylamine (NDMA) is classified as a substance that could cause cancer based on results from lab tests. NDMA is a known environmental contaminant and is found in water and foods (including meats, dairy products, vegetables).

Metformin is used as an add-on to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. The recalled metformin ER 750 mg tablets are packaged in plastic bottles of 100 tablets with NDC 29033-056-01. The recalled tablets carry lot number MET200501 with expiration date 07/2022. The product can be identified as an off-white oblong tablet debossed with “NM7”.

Consumers should consult a healthcare professional (HCP) to obtain a replacement or a different treatment option. It could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their HCP. Consumers should contact their physician or HCP if they have experienced any problems that may be related to taking this drug product.

Consumers with medical questions regarding this recall can contact Nostrum Medical Affairs at phone number 816-308-4941 or email quality@nostrumpharma.com Monday through Friday from 8 am – 5 pm CST. Consumers should contact their physician or pharmacy for further medical advice.

For more information regarding this FDA Recall Notification, please refer to the FDA website:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-expands-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets

FDA contact information for reporting adverse events/quality complaints can be reached online at
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.