Nostrum Expands Voluntary Nationwide Recall of Metformin HCl Extended Release Tablets, USP 750 mg, Due to NDMA Content Above the Acceptable Daily Intake Limit

FDA Publish Date: 1/4/2021

Nostrum Laboratories is voluntarily recalling one (1) lot of metformin hydrochloride (HCl) extended release (ER) tablets, USP 750 mg (generic equivalent to Glucophage® tablets) to the consumer level. The metformin HCl ER tablets, USP 750 mg have been found to contain levels of nitrosamine impurities above the acceptable daily intake (ADI) limit of 96 ng/day as published in the Food and Drug Administration (FDA) Guidance Document issued September 2020. This is an expansion of the recall initially announced on November 2, 2020.

N-Nitrosodimethylamine (NDMA) is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and is found in water and foods (including meats, dairy products, vegetables). To date, Nostrum has not received any reports of adverse events related to this recall.

The product is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus and is packaged in high density polyethylene (HDPE) bottles of 100 tablets, under NDC 29033-056-01. The affected lot of metformin HCl ER tablets, USP 750 mg is listed in the table. The product can be identified as an off-white oblong tablet debossed with “NM7”. Metformin HCl ER tablets, USP 750 mg was distributed nationwide to wholesalers.

Product Description	NDC	Lot Number	Expiry Date
Metformin HCl Extended Release Tablets, USP 750 mg	29033-056-01	MET200501	07/2022

Nostrum is notifying its distributors by letter and is arranging for return of all recalled products. Pharmacies that have metformin HCl ER tablets, USP 750 mg which are being recalled should return to place of purchase. 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 by phone at 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the United States (US) FDA.

Link to FDA recall notification: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-expands-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets

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Company Contact Information

Consumers:

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Product Photos

Click here for product photos.