Nostrum Issues Voluntary Nationwide Recall of Metformin HCl Extended Release Tablets, USP 500 mg and 750 mg, Due to NDMA Content Above the Acceptable Daily Intake Limit

Date: 11/2/2020

Nostrum Laboratories, Inc. is voluntarily recalling 2 lots of Metformin Hydrochloride (HCl) Extended Release (ER) Tablets, USP 500 mg and 2 lots of Metformin HCl ER Tablets, USP 750 mg to the consumer level. The Metformin HCl ER Tablets, USP 500 mg and 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 FDA Guidance Document issued September 2020.

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, and vegetables). Nostrum has not received any reports of adverse events related to this recall.

Metformin HCl ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. Product is packaged in HDPE bottles of 100 tablets, with NDC 29033-055-01 (500 mg) or NDC 29033-056-01 (750 mg). The affected Metformin HCl ER Tablets, USP 500 mg and 750 mg lots are listed in the table below.

Product Description	NDC	Lot Numbers	Expiry Dates
Metformin HCl Extended Release Tablets, USP 500 mg	29033-055-01	MET100201	05/2022
		MET100401	05/2022
Metformin HCl Extended Release Tablets, USP 750 mg	29033-056-01	MET200101	05/2022
		MET200301	05/2022

The 500 mg product can be identified as an off-white oblong tablet debossed with “NM5”, and the 750 mg product can be identified as an off-white oblong tablet debossed with “NM7”. Metformin HCl ER Tablets, USP 500 mg and 750 mg were distributed nationwide to wholesalers.

Nostrum is notifying its distributors by letter and is arranging for return of all recalled products. Pharmacies that have Metformin HCl ER Tablets, USP 500 mg or 750 mg which are being recalled should return to the 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 at phone number 816-308-4941 or via email at quality@nostrumpharma.com Monday through Friday from 8 am to 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) Food and Drug Administration.

Links to FDA recall notifications

- 500 mg: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0
- 750 mg: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets

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Company Contact Information

Consumers:

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