COMPANY ANNOUNCEMENT

Nostrum Laboratories, Inc. Issues Voluntary Nationwide Recall of Metformin HCl Extended Release Tablets, USP 750 mg, Due to N-Nitrosodimethylamine (NDMA) Content Above the Acceptable Daily Intake (ADI) Limit

Summary

Company Announcement Date:

November 02, 2020

FDA Publish Date:

November 02, 2020

Product Type:

Drugs

Reason for Announcement:

NDMA exceeds acceptable daily intake limit

Company Name:

Nostrum Laboratories

Brand Name:

Nostrum Laboratories

Product Description:

Metformin HCl Extended Release Tablets, USP 750 mg

Company Announcement

Kansas City, Missouri, Nostrum Laboratories, Inc. is voluntarily recalling 2 (two) lots of Metformin HCl Extended Release Tablets, USP 750 mg to the consumer level. The Metformin HCl Extended Release Tablets, USP 750 mg have been found to contain levels of nitrosamine

impurities above the 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 found in water and foods, including meats, dairy products, and vegetables. Nostrum Laboratories, Inc. 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 HDPE bottles of 100 tablets, under NDC 29033-056-01. The affected Metformin HCl Extended Release Tablets, USP 750 mg lots are listed in the table below. The product can be identified as an off-white oblong tablet debossed with "NM7". Metformin HCl Extended Release Tablets, USP 750 mg was distributed Nationwide to wholesalers.

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

Nostrum Laboratories, Inc. is notifying its distributors by letter and is arranging for return of all recalled products. Pharmacies that have Metformin HCl Extended Release Tablets, USP 750 mg which is being recalled should return to place of purchase. Consumers should consult a healthcare professional 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 healthcare professional. Consumers should contact their physician or healthcare provider 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 Laboratories, Inc. Medical Affairs at phone number 816-308-4941 or email quality@nostrumpharma.com (mailto:quality@nostrumpharma.com) Monday through Friday from 8am – 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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 U.S. Food and Drug Administration.

Company Contact Information

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