ABARCA

January 5, 2021

To All Network Pharmacies

Notification of Drug Recall

Nostrum Laboratories, Inc. Expands 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

The U.S. Food and Drug Administration (FDA) provides public notices about recalls of FDA-regulated products, whenever it occurs. We are committed to our patients' health and safety. In order to keep you informed we are notifying you of the following recall.

Product	NDC Code	Batch number	Expiry Dates	Reason	Company
Metformin HCl Extended Release Tablets, USP 750 mg	29033-0056-01	MET200501	07/2022	NDMA exceeds acceptable daily intake limit	Nostrum Laboratories

We are including the *FDA Press Release/Announcement* for your convenience. Please refer to this document for more information.

Sincerely,

Providers Education Department
Abarca health LLC

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Company Announcement

Nostrum Laboratories, Inc. is voluntarily recalling one lot of Metformin HCl Extended Release Tablets, USP 750 mg (generic equivalent to Glucophage Tablets) to the consumer level. The Metformin HCl Extended Release Tablets, USP 750 mg (generic equivalent to Glucophage Tablets) 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. This is an expansion of the recall initially announced on November 2, 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. To date, 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 (generic equivalent to Glucophage Tablets) lot is 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 (generic equivalent to Glucophage Tablets) was distributed Nationwide to wholesalers.

Product Description	NDC	Lot Number	Expiry Dates
Metformin HCl Extended Release Tablets, USP 750 mg (generic equivalent to Glucophage Tablets)	29033-056-01	MET200501	07/2022

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 (generic equivalent to Glucophage Tablets) 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 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 U.S. Food and Drug Administration.