January 7, 2021 COM-2021-002

RECALL NOTIFICATION

FDA PUBLICATION DATE: January 4, 2021

DRUG NAME: Metformin Hydrochloride Extended-Release Tablets, USP 750mg

COMPANY: Nostrum Laboratories

REASON: Due to detection of NDMA above the ADI

Dear provider of pharmaceutical services,

PharmPix is committed to the health and well-being of patients. For this reason, we are notifying you that on January 4, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary recall for one lot of Metformin HCl Extended-Release Tablets, USP 750 mg, manufactured by Nostrum Laboratories, Inc.

Affected product:

NDC	Product description	Lot #	Expiration Date
29033-0056-01	Metformin HCl Extended Release Tablets, USP 750 mg (generic equivalent to Glucophage Tablets)	MET200501	07/2022

The voluntary recall is due to the detection of levels of nitrosamine impurities above the acceptable daily intake (ADI) limit of 96 ng/day. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products, and vegetables, and is classified as a probable human carcinogen. Patients 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.

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Pharmacy required actions(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returning to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- Advise patients to contact their healthcare provider if they have experienced any problems related to using this drug product.

Contact information: For further details, contact Nostrum Laboratories, Inc. Medical Affairs at phone number 816-308-4941 or email quality@nostrumpharma.com.

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download the FDA Form 3500 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.

Additional information can be found at:

- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-expands-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2021). 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. Retrieved January 6, 2021, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-expands-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets