November 4, 2020 COM-2020-086

RECALL NOTIFICATION

FDA PUBLICATION DATE: November 2 & 4, 2020

DRUG NAME: Metformin Hydrochloride Extended-Release Tablets, USP 500mg and 750mg

COMPANY: Nostrum Labs

REASON: Due to detection of NDMA above the ADI

Dear provider of pharmaceutical services,

At PharmPix, we are committed to the health and well-being of patients. It is for this reason that we are notifying you that on November 2, 2020, the U.S. Food and Drug Administration (FDA) published a voluntary recall for two lots of Metformin HCl Extended-Release Tablets, USP 750 mg, and two lots of the Metformin HCl Extended-Release Tablets, USP 500 mg, manufactured by Nostrum Laboratories, Inc.

Affected product:

NDC	Product description	Lot #	Expiration Date
29033-055-01	Metformin HCl Extended Release Tablets, USP 500 mg, 100 Count	MET100201 MET100401	05/2022 05/2022
29033-056-01	Metformin Hydrochloride Extended-Release Tablets, USP 750mg, 100 Count	MET200101 MET200301	05/2022 05/2022

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. 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.

Pharmacy required actions(s):

- Identify if the product is 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.

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- For further information: Contact Nostrum Laboratories, Inc. Medical Affairs at phone number: 816-308-4941 or email: quality@nostrumpharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems related to using this drug product.

Contact information:

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:

- FDA Recall for Metformin
- FDA Recall for Metformin
- 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. (2020). 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. Retrieved November 4, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets
- U.S. Food and Drug Administration. (2020). Nostrum Laboratories, Inc. Issues Voluntary Nationwide Recall of Metformin HCl Extended Release Tablets, USP 500 mg, Due to N-Nitrosodimethylamine (NDMA) Content Above the Acceptable Daily Intake (ADI) Limit. Retrieved November 4, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nostrum-laboratories-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0

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