Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 11/3/2020

Brief Description of Recall Alert

Nostrum Laboratories, Inc. is voluntarily recalling two (2) lots of metformin HCl extended release tablets, USP 500 mg to the consumer level. The metformin HCl extended release tablets, USP 500 mg have been found to contain levels of nitrosamine impurities above the ADI limit of 96 mg/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 29033-055-01. The affected metformin HCl extended release tablets, USP 500 mg lots are listed in the table below. The product can be identified as an off-white oblong tablet debossed with “NM5”. Metformin HCl Extended Release Tablets, USP 500 mg was distributed nationwide to wholesalers.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin HCl extended release tablets, USP 500 mg	29033-055-01	MET200101	05/2022
metformin HCl extended release tablets, USP 500 mg	29033-055-01	MET100401	05/2022

Prescriber Information

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 500 mg which is being recalled should be returned to the 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.

Adverse reactions or issues experienced with the use of this drug 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

Member Information

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 8am – 5 pm CST. Consumers should contact their physician or pharmacy for further medical advice.

Members should contact their doctor if they have experienced any problems that may be related to taking or using this drug.

RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option.