metformin hydrochloride ER tablets Recall Alert

Date of Notice: 11/02/2020

Brief Description of Recall Alert

Nostrum Laboratories, Inc. is voluntarily recalling two (2) lots of metformin hydrochloride (HCl) extended release (ER) tablets, USP 750 mg. The recalled lots have been found to contain levels of N-Nitrosodimethylamine (NDMA) impurities above acceptable limits.

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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin HCl ER tablets, USP 750 mg	29033-056-01	MET200101	05/2022
metformin HCl ER tablets, USP 750 mg	29033-056-01	MET200301	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 750 mg which is being recalled should return to place of purchase. Nostrum Laboratories, Inc. has not received any reports of adverse events related to this recall.

Adverse reactions or quality problems 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

Members 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.

Members should consult with their doctor to obtain a replacement or a different treatment option. 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. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.