

metformin hydrochloride ER tablets Recall Alert

Date of Notice: 01/04/2021

Brief Description of Recall Alert

Nostrum Laboratories, Inc. is voluntarily recalling one lot of metformin HCl extended-release (ER) tablets, USP 750 mg. The metformin HCl ER tablets, USP 750 mg been found to contain levels of nitrosamine impurities above the acceptable daily limit. 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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin HCl ER tablets, USP 750 mg	29033-056-01	MET200501	07/2022

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 ER tablets, USP 750 mg which is being recalled should return to place of purchase. To date, 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.

nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides a 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.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

© 2020 RxAdvance Corporation. Confidential and Proprietary.