RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 08/20/2020

Brief Description of Recall Alert

Bayshore Pharmaceuticals, LLC is voluntarily recalling one lot of metformin hydrochloride (HCl) extended-release (ER) tablets, USP 500 mg and one lot of metformin HCl ER tablets, USP 750 mg due to the detection of N-Nitrosodimethylamine (NDMA) levels above the acceptable daily intake limit levels. This product was manufactured by Beximco Pharmaceuticals Limited, Dhaka, Bangladesh in June 2019, for U.S. distribution by Bayshore.

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 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 500 mg	76385-128-10	18641	05/2021
metformin HCl ER tablets, USP 750 mg	76385-129-01	18657	05/2021

Prescriber Information

To date, neither Bayshore nor Beximco have received any reports of adverse events related to use of the product.

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

Bayshore Pharmaceuticals, LLC is in the process of notifying its customers affected by this recall by phone and through recall notification and is arranging for return of the entire recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

Customers and patients with medical-related questions, who wish to report an adverse event, or quality issues about the products being recalled should contact Bayshore Pharmaceuticals LLC Information by phone at: 877-372-6093.

Patients wishing to return products may contact Bayshore's product recall processor Qualanex, LLC to obtain instructions and a return kit for returning their medication:

- Contact Qualanex at 888-504-2013
- Qualanex will provide the materials needed to return their medication and instructions for reimbursement

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall. Members should continue taking metformin until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option.