Bayshore Pharmaceuticals Issues Voluntary Nationwide Recall of Metformin ER Tablets 500 mg and 750 mg Due to NDMA Impurity

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Bayshore Pharmaceuticals is voluntarily recalling one (1) lot of Metformin Hydrochloride (HCl) Extended-Release (ER) Tablets USP, 500 mg, in 1000-count bottles and one (1) lot of Metformin HCl ER Tablets USP, 750 mg, in 100-count bottles within expiry to the consumer level due to the detection of N-Nitrosodimethylamine (NDMA) levels above the acceptable daily intake (ADI) Limit. This product was manufactured by Beximco in June 2019, for United States (US) distribution by Bayshore.

Bayshore was notified by the US Food and Drug Administration (FDA) that 1 lot (lot #18657) of metformin HCl ER tablets, 750 mg, was tested and showed NDMA levels in excess of the ADI limit and recommended recall of the 1 tested lot.

Bayshore has agreed to recall this lot, and out of an abundance of caution, the company has tested samples from 8 lots of metformin HCl ER tablets manufactured using same active pharmaceutical ingredient (API) lot of the failed lot. Out of 8 lots, 1 lot (lot #18657) of metformin HCl ER tablets, 750 mg, and 1 lot (lot #18641) of metformin HCl ER tablets, 500 mg, have showed NDMA levels in excess of the ADI limit. As a result, Bayshore has decided to recall the 2 lots. To date, neither Bayshore nor Beximco have received any reports of adverse events related to use of the product.

Risk Statement: 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 is found in water and foods (such as meats, dairy products, and vegetables).

Metformin HCl ER tablets USP, 500 mg and 750 mg, are indicated as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus. Patients who have received impacted lots of metformin ER tablets are advised by the manufacturer to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment. According to the FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare professionals. Please visit the agency's website for more information at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin.

The metformin HCl ER tablets, 500 mg and 750 mg, lots subject to the recall are identified in the table below.

Product Name	Strength	Bottle Size	NDC Number	Lot #	Expiration
Metformin HCl ER Tablets USP, 500 mg	500 mg	1000-count	76385-0128-10	18641	May 2021
Metformin HCl ER Tablets USP, 750 mg	750 mg	100-count	76385-0129-01	18657	May 2021

The impacted metformin HCl ER tablet lots were distributed nationwide in the US by Bayshore directly to wholesalers and distributors. Bayshore is in the process of notifying its customers impacted by this recall by phone and through recall notification and is arranging for return of the 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 issue about the products being recalled should contact **Bayshore by phone at 877-372-6093.**

Patients wishing to return product may contact Bayshore's product recall processor, **Qualanex**, 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

Adverse reactions or quality problems experienced with the use of this product 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

Patient safety and product quality are critical to Bayshore. Bayshore will continue to partner with, and regularly update, all relevant regulatory authorities as relevant information becomes available.

Company Contact Information

Consumers:

Qualanex, Bayshore Pharmaceuticals LLC Information

888-504-2013, 877-372-6093

Product Photos

For Product photos please refer to the FDA Link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayshore-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended