COMPANY ANNOUNCEMENT

Bayshore Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 750 mg Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

Summary

Company Announcement Date:

August 19, 2020

FDA Publish Date:

August 20, 2020

Product Type:

Drugs

Reason for Announcement:

Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

Company Name:

Bayshore Pharmaceuticals, LLS

Brand Name:

Bayshore Pharmaceuticals, LLS

Product Description:

Metformin Hydrochloride Extended-Release Tablets USP, 500 mg & 750 mg

Company Announcement

Bayshore Pharmaceuticals, LLC, Short Hills, NJ is voluntarily recalling one (1) lot of Metformin Hydrochloride Extended-Release Tablets USP, 500 mg, 1000 count bottles and one (1) lot of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, 100 count bottles within

expiry to the consumer level due to the detection of N-Nitrosodimethylamine (NDMA) levels above the Acceptable Daily Intake Limit. This product was manufactured by Beximco Pharmaceuticals Limited, Dhaka, Bangladesh in June 2019, for U.S. distribution by Bayshore.

Bayshore was notified by the U.S. Food and Drug Administration (US FDA) that one lot (Lot number 18657) of Metformin Hydrochloride Extended-Release Tablets, USP 750 mg was tested and showed results for N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI) and recommended recall of the one tested lot.

Bayshore has agreed to recall this lot, and out of an abundance of caution, the company has tested samples from eight (8) lots of Metformin Hydrochloride Extended-Release Tablets manufactured using same API lot of the failed lot. Out of eight (8) lots, one lot (Lot number 18657) of Metformin Hydrochloride Extended-Release Tablets, USP 750 mg and one lot (Lot number 18641) of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg have showed N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI). Hence, Bayshore has decided to recall the two lots (Lot number 18641 and 18657). 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 found in water and foods, including meats, dairy products, and vegetables.

Metformin Hydrochloride Extended-Release 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 Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg are advised 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 (https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin).

The Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 750 mg lots subject to the recall are identified in the table below.

Product Name	Strength	Pack Size	NDC Number	Lot Number	Expiration
Metformin Hydrochloride Extended-Release Tablets USP, 500 mg	500 mg	1000's Bottle	76385-128-10	18641	MAY 2021

Product Name	Strength	Pack Size	NDC Number	Lot Number	Expiration
Metformin Hydrochloride Extended-Release Tablets USP, 750 mg	750 mg	100's Bottle	76385-129-01	18657	MAY 2021

The affected Metformin Hydrochloride Extended-Release Tablets USP, 500 mg 750 mg, lots were distributed nationwide in the USA by Bayshore directly to Wholesalers and Distributors. 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 product 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.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

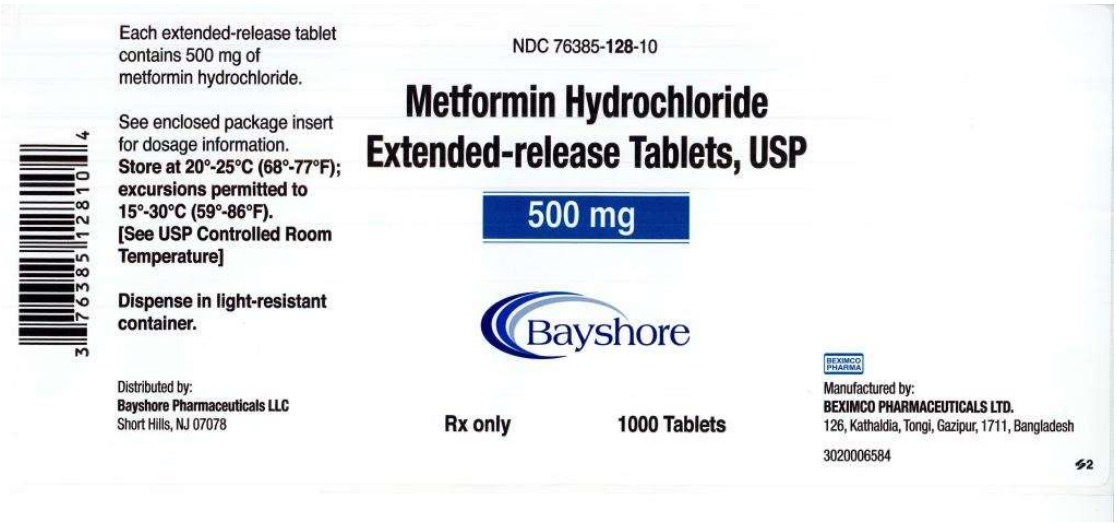
Company Contact Information

Consumers:

Qualanex, Bayshore Pharmaceuticals LLC Information

888-504-2013, 877-372-6093

Product Photos



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