

Metformin ER 500 mg and 750 mg Tablets

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Bayshore has posted a lot recall of Metformin Hydrochloride (HCl) Extended-Release (ER) Tablets, 500 mg and 750 mg.

About this Recall:

Bayshore Pharmaceuticals is voluntarily recalling one (1) lot of metformin HCl ER tablets, 500 mg, and one (1) lot of metformin HCl ER tablets, 750 mg, within expiration to the consumer level. The recall is due to 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.

What this means to you:

NDMA is 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). The impacted metformin ER tablets can be identified by the NDC number found on the product label and the product lot number. The recalled NDC and lot numbers are listed on the FDA Recall Notification at the link below. 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.

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

For more information regarding this FDA Recall Notification, please refer to the FDA website:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayshore-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended>

FDA contact information for reporting adverse events/quality complaints can be reached online at <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home> or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.