



Bayshore Pharmaceuticals – Recall of metformin extended-release (ER)

- On August 19, 2020, [Bayshore announced](#) voluntary, consumer-level recall of two lots of [metformin ER](#) 500 mg and 750 mg tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit.
- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
- There are over 30 different manufacturers of metformin ER and Bayshore accounts for a small portion of the marketplace.
- The recalled lots were manufactured by Beximco Pharmaceuticals in June 2019, for distribution by Bayshore.

Product Description	NDC#	Lot#
Metformin Hydrochloride Extended-Release 500 mg tablets	76385-128-10	18641 (5/2021)
Metformin Hydrochloride Extended-Release 750 mg tablets	76385-129-10	18657 (5/2021)

- Metformin ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.
- Patients who have the recalled metformin ER should continue taking it and contact their physician or healthcare provider to prescribe a replacement.
- Health care professionals should continue to prescribe metformin when clinically appropriate. FDA testing has not shown NDMA in immediate release (IR) metformin products (the most commonly prescribed type of metformin).
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- The FDA continues to evaluate the safety of metformin and will provide more information as it becomes available. Updates can be found [here](#).
- Contact Bayshore by phone at **1-877-372-6093** for further information regarding this recall.

- 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 at **1-888-280-2013**.



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