

## **Metformin Hydrochloride Extended Release Tab – Teva Pharmaceuticals USA, Inc.**

On June 2, 2020, the U.S. Food and Drug Administration (FDA) announced that Teva Pharmaceuticals USA, Inc. is voluntarily recalling fourteen lots of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg to the consumer-level due to the detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI).

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 is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.

The affected Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, being recalled are described as:

- Metformin Hydrochloride Extended-Release Tablets, USP 500 mg, white to off-white capsule shaped tablets, debossed with an Andrx logo with “571” on one side and “500” on the opposite side.
- Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, light yellow capsule shaped tablets, debossed with an Andrx logo with “577” on one side and “750” on the opposite side.

Teva is notifying its distributors and customers affected by this recall via FedEx overnight mailing. Patients taking 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 US Food & Drug Administration, It could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals.

Customers and patients with medical-related questions, who wish to report an adverse event, or quality issues about the Teva products being recalled should contact Teva Medical Information by phone at: 888-838-2872, option 3, then, option 4. Live calls are received Monday-Friday, 9:00 am to 5:00 pm Eastern Time with voicemail available 24 hours/day, 7 days/week or by email at [druginfo@tevapharm.com](mailto:druginfo@tevapharm.com) (mailto:druginfo@tevapharm.com).