Teva Pharmaceuticals Initiates Voluntary Nationwide Recall of Metformin ER Tablets 500 mg and 750 mg Due to Detection of NDMA

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Teva Pharmaceuticals is voluntarily recalling fourteen (14) lots of Metformin Hydrochloride Extended-Release (ER) Tablets, USP 500 mg and 750 mg, 100 and 1000 count bottles, in the United States (US) to the consumer level due to the detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake (ADI) Limit.

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 lots being recalled are packaged under the Actavis Pharma, Inc. label and are contained in the table below. They were distributed nationwide in the US as retail bottles of 100 tablets and 1,000 tablets to Teva's direct customers between January 8, 2019 and May 27, 2020.

The affected Metformin ER 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

NDC	Product Description	Lot Number	Expiration
62037-0571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1329548A	06/2020
		1338302M	10/2020
		1348968M	10/2020
		1348969M	11/2020
		1348970M	10/2020
		1376339M	09/2021
62037-0571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1323460M	06/2020
		1330919M	06/2020
		1338300A	10/2020
		1341135M	12/2020
		1391828M	11/2021
62037-0577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100 Count	1333338M	08/2020
		1333339A	08/2020
62037-0577-10	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 1000 Count	1354471A	02/2021

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 (FDA), it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare professional. 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.

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 1-888-838-2872, option 3, then, option 4. Live calls are received Monday through Friday, 9:00 AM to 5:00 PM Eastern Time with voicemail available 24 hours a day, 7 days a week or by email at druginfo@tevapharm.com.

Patients wishing to return product may contact Teva's product recall processor (Inmar) to obtain instructions and a return kit for returning their medication:

- Contact Inmar at 1-855-532-1850 (9 AM to 5 PM Eastern Time, Monday to Friday) or email Inmar at tevarecalls@inmar.com
- Inmar will provide the materials needed to return the 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

This recall is being conducted with the knowledge of the US FDA.

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

Company Contact Information

Consumers:

Teva's Medical Information

888-838-2872

druginfo@tevapharm.com

Media:

Kelley Dougherty, Eric Rubin

973-832-2819, 862-221-7151

Product Photos

For Product photos please refer to the FDA Link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-initiates-voluntary-nationwide-recall-metformin-hydrochloride-extended?utm_campaign=Teva%20Pharmaceuticals%20USA%2C%20Inc.%20Initiates%20Voluntary%20Nationwide%20Recall%20of%20Metformin%20Hydrochloride&utm_medium=email&utm_source=Eloqua