



**Voluntary Recall of**  
**Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg**  
**Consumer Level**  
**June 02, 2020**

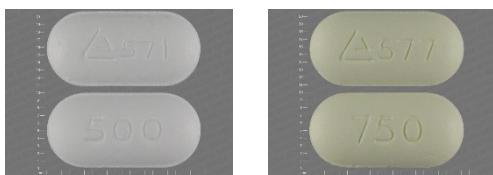
**Dear Valued Consumer/Patient/Caregiver:**

At Teva Pharmaceuticals USA, Inc. ("Teva"), our first priority is to our customers and patients. We are committed to providing patients and customers with access to affordable high-quality medicines that are both safe and effective.

On June 02, 2020, Teva initiated a voluntary **consumer level** recall for fourteen (14) lots of **Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, 100 and 1000 count bottles** which were distributed to Teva's customers from January 8, 2019 through May 27, 2020. (For the recalled lots details, see table on page 2). The lots are being recalled 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 is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. Patients taking Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, are advised to continue taking their medication and contact their health care professional who can prescribe a replacement. According to the US Food & Drug Administration (the "FDA"), it could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their health care professionals.

**The Metformin Hydrochloride Extended-Release Tablets, USP being recalled have the appearance of:**

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



Only the lots of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg listed on page 2 are affected by this voluntary recall. No other Metformin Hydrochloride Extended-Release products marketed or manufactured by Teva Pharmaceuticals for the US market are impacted by this voluntary recall.

Once your physician has identified a replacement medication to treat your condition, we request that you return any remaining product in your possession. Please contact Teva's product recall processor to obtain instructions and a kit for returning your medication: Inmar at 855-532-1850 (Hours of operation 9:00 am to 5:00 pm Eastern Time, Monday – Friday) or email Inmar at [tevarecalls@inmar.com](mailto:tevarecalls@inmar.com). Inmar will provide the materials needed to return your medication in a pre-paid mailer and instructions for your reimbursement. Please make sure you only return recalled product listed below. The cost of any drug products that are received which are *not* the subject of this recall will not be reimbursed.

If you wish to report an Adverse Event or Quality Complaint, or have Medical Related Questions, please contact Teva's Medical Information at: 888-838-2872, option 3, then, option 4. Live calls are received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time and voicemail: 24 hrs./day, 7 days/week or by email at [druginfo@tevapharm.com](mailto:druginfo@tevapharm.com). Adverse reactions or other problems experienced with the use of this product may also 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**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax**: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) 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-1088.

Sincerely,  
Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

**DRUG PRODUCT RECALL**  
**Information for Consumers/Patients/Caregivers**

NDC	Product Description	Lot Number	Expiration Date
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1329548A	06/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1338302M	10/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1348968M	10/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1348969M	11/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1348970M	10/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1376339M	09/2021
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1323460M	06/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1330919M	06/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1338300A	10/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1341135M	12/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1391828M	11/2021
62037-577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100 Count	1333338M	08/2020
62037-577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100 Count	1333339A	08/2020
62037-577-10	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 1000 Count	1354471A	02/2021