**June 8, 2020** **COM-2020-043**

# RECALL NOTIFICATION

## FDA Publish Date:
**June 5, 2020**

## DRUG NAME:
**Metformin Hydrochloride Extended-Release Tablets, USP 500mg and 750mg**

## COMPANY:
**Teva Pharmaceuticals USA Inc.**

## REASON:
**Due to the detection of N-Nitrosodimethylamine (NDMA)**

**Dear provider of pharmaceutical services,**

At PharmPix, we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

**Affected product:**

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

**Pharmacy required action:**

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication.
- Advise patients to continue taking their medication and to contact their physician for advice regarding an alternative treatment, and if they have experienced any problems that may be related to taking or using the recalled drug product.

**Contact information:**

- Consumers and Patients (for medical questions): Contact Teva Medical Information by phone at 888-838-2872, option 3, then option 4. Monday-Friday, 9:00 am to 5:00 pm ET, or by email at druginfo@tevapharm.com.
- Patients (for product return): Contact Inmar at 1-855-532-1850 (9 am to 5 pm ET, Monday – Friday) or email Inmar at tevarecalls@inmar.com

**Note:**
Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch

Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm

- Regular Mail or Fax: Download form 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-0178

**Additional information:**
https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls

Best regards,

**PharmPix Clinical Department**

Reference:


- *Center for Drug Evaluation and Research. (2020, June 5). Teva Pharmaceuticals USA, Inc. Initiates Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets USP 500 mg and 750 mg Due to Detection of N-Nitrosodimethylamine (NDMA)*. Retrieved June 8, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-initiates-voluntary-nationwide-recall-metformin-hydrochloride-extended?utm_campaign=Teva%20Recall%20Metformin%20Hydrochloride%20Extended-Release%20Tablets%20USP%2C%20500%20mg%20and%20750mg&utm_medium=email&utm_source=Eloqua




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