RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 06/02/2020

Brief Description of Recall Alert

Teva Pharmaceuticals USA, Inc. is voluntarily recalling fourteen (14) lots of metformin hydrochloride extended-release tablets, USP 500 mg and 750 mg, due to the detection of N-Nitrosodimethylamine (NDMA) levels above acceptable amounts.

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 found in water and foods, including meats, dairy products and vegetables.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin HCl ER tablets, USP 500 mg	62037-571-01	1329548A	06/2020
metformin HCl ER tablets, USP 500 mg	62037-571-01	1338302M	10/2020
metformin HCl ER tablets, USP 500 mg	62037-571-01	1348968M	10/2020
metformin HCl ER tablets, USP 500 mg	62037-571-01	1348969M	11/2020
metformin HCl ER tablets, USP 500 mg	62037-571-01	1348970M	10/2020
metformin HCl ER tablets, USP 500 mg	62037-571-01	1376339M	09/2021
metformin HCl ER tablets, USP 500 mg	62037-571-10	1323460M	06/2020
metformin HCl ER tablets, USP 500 mg	62037-571-10	1330919M	06/2020
metformin HCl ER tablets, USP 500 mg	62037-571-10	1338300A	10/2020
metformin HCl ER tablets, USP 500 mg	62037-571-10	1341135M	12/2020
metformin HCl ER tablets, USP 500 mg	62037-571-10	1391828M	11/2021
metformin HCl ER tablets, USP 750 mg	62037-577-01	1333338M	08/2020
metformin HCl ER tablets, USP 750 mg	62037-577-01	1333339A	08/2020
metformin HCl ER tablets, USP 750 mg	62037-577-10	1354471A	02/2021

Prescriber Information

Adverse reactions or quality problems experienced with the use of this drug 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

Member Information

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 drug and contact their pharmacist or doctor for advice regarding an alternative treatment. According to the FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their doctor. 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: 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.

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

Contact Inmar at 1-855-532-1850 (Hours of Operation: 9 am to 5 pm Eastern Time, Monday – Friday) or email Inmar at: tevarecalls@inmar.com.

Inmar will provide the materials needed to return their drug and instructions for reimbursement.

RxAdvance Response

RxAdvance has reviewed prescription claims and did not find any members impacted by this recall.