RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 5/29/2020

Brief Description of Recall Alert

Amneal Pharmaceuticals LLC Bridgewater, New Jersey (Amneal), is voluntarily recalling all lots of metformin hydrochloride extended release (ER) tablets, USP, 500 mg and 750 mg.

Amneal was notified by the FDA that the testing of seven lots of metformin hydrochloride ER tablets showed N-Nitrosodimethylamine (NDMA) amounts above acceptable levels. The FDA has recommended the recall of the seven tested lots. Amneal has agreed to this recall and extended the recall to all lots within out of an abundance of caution.

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	53746-178-01	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	53746-178-05	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	53746-178-10	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	53746-178-90	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	53746-178-Bulk	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	65162-178-09	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	65162-178-10	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	65162-178-11	All lots	All dates
metformin HCl ER Tablets, USP, 500 mg	65162-178-50	All lots	All dates
metformin HCl ER Tablets, USP, 750 mg	53746-179-01	All lots	All dates
metformin HCl ER Tablets, USP, 750 mg	53746-179-Bulk	All lots	All dates
metformin HCl ER Tablets, USP, 750 mg	65162-179-10	All lots	All dates

Prescriber Information

To date, Amneal has not received any reports of adverse events that have been confirmed to be directly related to this recall. Amneal's metformin hydrochloride immediate release tablets, USP are not affected by this recall.

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

Member Information

Amneal is notifying its direct customers by mailing a recall notification letter and is arranging for return of all the recalled drug. Anyone with an existing inventory of the drug should quarantine the recalled lots immediately.

Customers who purchased the impacted product directly from Amneal may call Amneal at 1-833-582-0812 or email to AmnealproductrecallDS@amneal.com, Monday – Friday, 8:00 am – 5:00 pm, EST, for further information.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise those impacted by this recall.