RXADVANCE
2 Park Central Drive
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Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 07/08/2020

Brief Description of Recall Alert

Lupin Pharmaceuticals Inc. is voluntarily recalling all batches of metformin hydrochloride extended-release tablets USP, 500mg and 1000mg to the consumer level. As part of the ongoing assessment and continuation of the dialog with the FDA, additional analysis revealed that certain tested batches were above the Acceptable Daily Intake Limit for the impurity N-Nitrosodimethylamine (NDMA). Out of an abundance of caution, the company is recalling all batches of metformin hydrochloride extended-release tablets USP, 500mg and 1000mg in the US. To date, Lupin Pharmaceuticals Inc. has not received any reports of adverse events related to this recall.

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	68180-338-01	All lots	All dates
metformin HCl ER tablets, USP 500 mg	68180-336-07	All lots	All dates
metformin HCl ER tablets, USP 1000 mg	68180-339-09	All lots	All dates
metformin HCl ER tablets, USP 1000 mg	68180-337-07	All lots	All dates

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

Lupin Pharmaceuticals Inc. is notifying its wholesalers, distributors, and mail order pharmacies by phone and through recall notification and is arranging for the return of all the recalled product lots. Patients taking metformin hydrochloride extended-release tablets, USP 500 mg and 1000 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 U.S. Food & Drug Administration, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals. 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.

RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides a replacement drug (if needed) or a different treatment option.