June 12, 2020 **COM-2020-045**

RECALL NOTIFICATION

FDA Publish Date:
June 11, 2020

DRUG NAME:
Metformin Hydrochloride Extended-Release Tablets, USP 500mg

COMPANY:
Lupin Pharmaceuticals Inc.

REASON:
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
68180-336-07	Metformin Hydrochloride Extended-Release Tablets, USP 500mg (generic equivalent of Fortamet®), 500mg	G901203	12/2020

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:

- Retailers: Return product to Inmar Rx Solutions, Inc., 635 Vine St, Winston Salem, NC 27101. Tel: (855) 532-1856
- Consumers and Wholesalers for questions: Contact Inmar Rx Solutions, Inc. at (855) 532-1856Call: (855) 532-1856 Monday – Friday 09:00 am to 05:00 pm EST

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 11). Lupin Pharmaceuticals, Inc. Issues Voluntarily Nationwide Recall of One Lot of Metformin Hydrochloride Extended-Release Tablets USP, 500mg Due to the Detection of N-Nitrosodimethylamine (NDMA).* Retrieved June 12, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-one-lot-metformin-hydrochloride