July 8, 2020 COM-2020-052

RECALL NOTIFICATION

FDA PUBLICATION DATE: July 8, 2020

DRUG NAME:

Metformin Hydrochloride Extended-Release Tablets, 500mg and 1000mg

COMPANY: Lupin Pharmaceuticals, Inc.

REASON: Detection of N-Nitrosodimethylamine (NDMA)

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on July 8, 2020 the US Food and Drug Administration (FDA) published a drug recall for the following product(s):

Affected product	Strengths	NDC
Metformin Hydrochloride Extended-Release Tablets USP	500mg	68180-338-01
		68180-336-07
	1000mg	68180-339-09
		68180-337-07

Pharmacy required action(s):

- Identify if the product is 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 Inmar Rx Solutions, Inc. at (855) 532-1856 for the return of the recalled product.

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Contact information:

- Inmar Rx Solutions, Inc.
    - Phone: (855) 532-1856 Monday – Friday 09:00 am to 05:00 pm EST.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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 can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Lupin Pharmaceuticals, Inc. Issues Voluntarily Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets, 500mg and 1000mg Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity. U.S. Food and Drug Administration. (2020). Retrieved 8 July 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-metformin-hydrochloride-extended.

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