July 8, 2020

✔ **BSE Limited,**
Department of Corporate Services,
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
MUMBAI - 400 001.

The National Stock Exchange of India Ltd.,
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
MUMBAI - 400 051.

Dear Sir/Madam,

Re: Disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Subject: Lupin voluntarily recalls its Metformin Hydrochloride Extended-Release Tablets USP, 500mg and 1000mg products in the U.S.

The Company hereby notifies that it is voluntarily recalling its Metformin Hydrochloride Extended-Release Tablets USP, 500mg and 1000mg products in the U.S. This recall is being conducted out of an abundance of caution in line with the ongoing interaction with the U.S. Food and Drug Administration on NDMA impurity levels. The associated press release in the U.S. is attached for your reference.

Lupin's U.S. subsidiary Lupin Pharmaceuticals Inc. distributes Metformin Hydrochloride Extended-Release Tablets USP, 500mg and 1000mg in the U.S. We believe that the issues identified in the concerned products are addressable and we expect to re-introduce our updated Metformin Hydrochloride Extended-Release Tablet product(s) in the U.S. during the current quarter.

We wish to separately clarify that all of the company's Metformin products manufactured and marketed in India have been tested for NDMA levels and have been assessed to be safe for patients and comply with all relevant regulatory norms. Further, these aforementioned products are part of a completely separate supply chain with respect to their API source, formulation process and manufacturing sites.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

For **LUPIN LIMITED**

RAJVARDHAN VISHNU SATAM

Digitally signed by RAJVARDHAN VISHNU SATAM
Date: 2020.07.08 09:52:53 +05'30'

R. V. SATAM
COMPANY SECRETARY
(ACS - 11973)

Encl- : a/a.

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

Company Contact:
Arvind Bothra
Email: arvindbothra@lupin.com

Baltimore, Maryland, July 8, 2020: 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.

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

Metformin Hydrochloride Extended-Release Tablets USP is a prescription oral medication indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. Metformin Hydrochloride Extended-Release Tablets USP, 500mg and 1000mg is packaged in 60, 90 and 100 count bottles and was distributed nationwide in the US to wholesalers, distributors, drug chain, mail order pharmacies and supermarkets. The recalled NDC's are included in the table below:

Product	Strengths	NDC	Distribution Dates
Metformin Hydrochloride Extended-Release Tablets USP	500mg	68180-338-01	11/21/2018 - 05/27/2020
	1000mg	68180-339-09	
	500mg	68180-336-07	11/05/2018 - 05/22/2020
	1000mg	68180-337-07	

Lupin Pharmaceuticals Inc. is notifying its wholesalers, distributors, drug chain, mail order pharmacies and supermarkets by phone and through recall notification and is arranging for the return of all the recalled product NDC's.

Patients taking Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 1000mg, 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.

Wholesalers, distributors, and retailers that have Metformin Hydrochloride Extended-Release Tablets USP, 500mg and 1000mg that are being recalled should discontinue distribution of the recalled product NDC's immediately and return it to Inmar Rx Solutions, Inc., 635 Vine St, Winston Salem, NC 27101. Tel: (855) 532-1856.

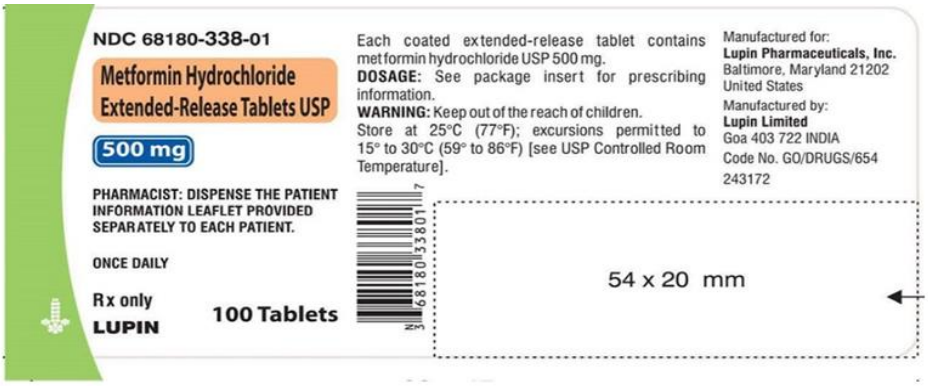
Consumers, wholesalers, distributors, and retailers with questions regarding this recall should contact Inmar Rx Solutions, Inc. at (855) 532-1856 Monday – Friday 09:00 am to 05:00 pm EST. For reimbursement, please have the recalled NDC's returned to Inmar Rx Solutions, Inc.; the NDC number can be found on the top of the bottle label.

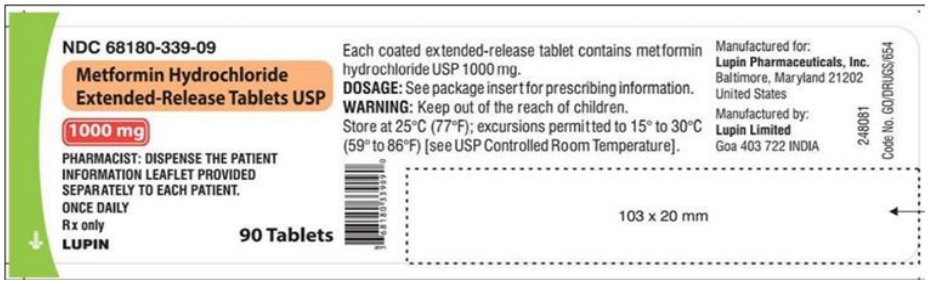
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

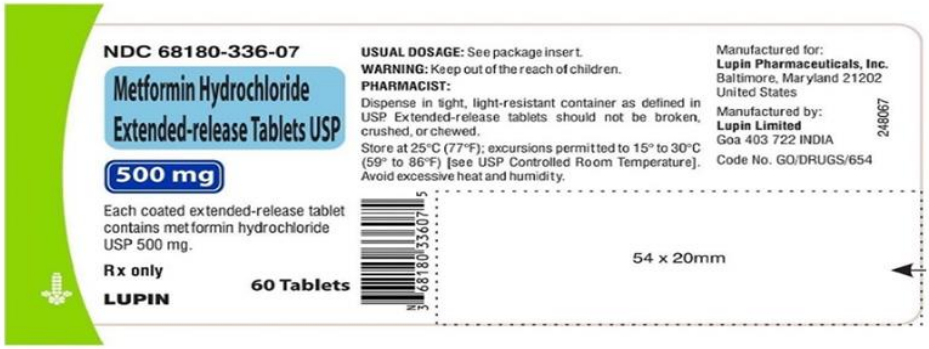
- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

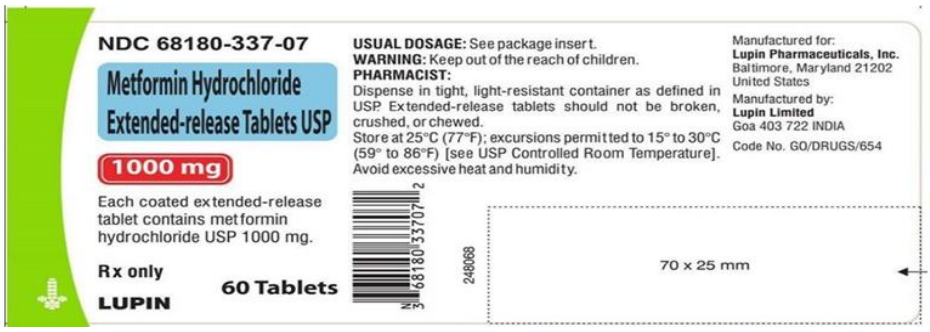
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Product Label:









About Lupin Pharmaceuticals

Lupin Pharmaceuticals, Inc. is the U.S. based wholly owned subsidiary of Lupin Limited and is the 3rd largest pharmaceutical company in the U.S. based on total prescriptions. Together, all Lupin-owned entities combine to make up the 8th largest generic pharmaceutical company in the world by revenue size. Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality medications across many treatment areas. Lupin Pharmaceuticals Inc.'s branded pharmaceuticals division, is the provider of products designed to help prevent and manage women's health conditions with serious health consequences.