

COMPANY ANNOUNCEMENT

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

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 08, 2020

FDA Publish Date:

July 08, 2020

Product Type:

Drugs

Reason for Announcement:

N-Nitrosodimethylamine (NDMA) Impurity

Company Name:

Lupin Pharmaceuticals, Inc.

Brand Name:

Lupin

Product Description:

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

Company Announcement

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> (<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin>).

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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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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.

Company Contact Information

Consumers:

Inmar, Rx Solutions, Inc.

☎ (855) 532-1856

Media:

Arvind Bothra

✉ arvindbothra@lupin.com (mailto:arvindbothra@lupin.com)

Product Photos

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NDC 68180-338-01

Metformin Hydrochloride Extended-Release Tablets USP

500 mg

PHARMACIST: DISPENSE THE PATIENT INFORMATION LEAFLET PROVIDED SEPARATELY TO EACH PATIENT.

ONCE DAILY

Rx only

LUPIN

100 Tablets

Each coated extended-release tablet contains metformin hydrochloride USP 500 mg.

DOSAGE: See package insert for prescribing information.

WARNING: Keep out of the reach of children.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:
Lupin Limited
Goa 403 722 INDIA
Code No. GO/DRUGS/654
243172

3 68180 33801 1 7

54 x 20 mm

NDC 68180-339-09

Metformin Hydrochloride Extended-Release Tablets USP

1000 mg

PHARMACIST: DISPENSE THE PATIENT INFORMATION LEAFLET PROVIDED SEPARATELY TO EACH PATIENT.

ONCE DAILY

Rx only

LUPIN

90 Tablets

Each coated extended-release tablet contains metformin hydrochloride USP 1000 mg.

DOSAGE: See package insert for prescribing information.

WARNING: Keep out of the reach of children.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:
Lupin Limited
Goa 403 722 INDIA

248081
Code No. GO/DRUGS/654

3 68180 33909 0 6

103 x 20 mm

NDC 68180-336-07

Metformin Hydrochloride Extended-release Tablets USP

500 mg

Each coated extended-release tablet contains metformin hydrochloride USP 500 mg.

Rx only

LUPIN

60 Tablets

USUAL DOSAGE: See package insert.

WARNING: Keep out of the reach of children.

PHARMACIST: Dispense in tight, light-resistant container as defined in USP Extended-release tablets should not be broken, crushed, or chewed.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Avoid excessive heat and humidity.

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:
Lupin Limited
Goa 403 722 INDIA

Code No. GO/DRUGS/654

248067

3 68180 33607 1 5

54 x 20mm

NDC 68180-337-07

Metformin Hydrochloride Extended-release Tablets USP

1000 mg

Each coated extended-release tablet contains metformin hydrochloride USP 1000 mg.

Rx only

LUPIN

60 Tablets

USUAL DOSAGE: See package insert.

WARNING: Keep out of the reach of children.

PHARMACIST: Dispense in tight, light-resistant container as defined in USP Extended-release tablets should not be broken, crushed, or chewed.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Avoid excessive heat and humidity.

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:
Lupin Limited
Goa 403 722 INDIA

Code No. GO/DRUGS/654

248068

3 68180 33707 1 2

70 x 25 mm

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