



# Lupin Pharmaceuticals, Inc.

## URGENT: DRUG RECALL

### **Metformin Hydrochloride Extended-Release Tablets USP, 500mg Metformin Hydrochloride Extended-Release Tablets USP, 1000mg**

July 17, 2020

Dear Valued Patient:

This is to inform you of a product recall involving Metformin Hydrochloride Extended-Release Tablets USP, 500mg and Metformin Hydrochloride Extended-Release Tablets USP, 1000mg, specifically for NDC 68180-336-07, 68180-337-07, 68180-338-01 and 68180-339-09 shipped from Lupin Pharmaceuticals, Inc. starting on November 7, 2018.

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 was distributed nationwide in the USA to wholesalers, distributors, drug chain, mail order pharmacies and supermarkets. The recalled lots are included below:

#### **Metformin HCl Extended Release Tablets USP, 500mg; NDC: 68180-338-01 (100's)**

Lot Number	Exp. Date	Lot Number	Exp. Date	Lot Number	Exp. Date
G808201	Aug-20	G901006	Dec-20	G908604	Oct-21
G808202	Aug-20	G904803	May-21	G002108	Jan-22
G808200	Aug-20	G904804	May-21	G002109	Jan-22
G900935	Dec-20	G906551	Jul-21	G002559	Feb-22
G901311	Dec-20	G906552	Jul-21	G002560	Feb-22
G900957	Dec-20	G907375	Aug-21		
G900958	Dec-20	G908605	Oct-21		

#### **Metformin HCl Extended Release Tablets USP, 1000mg; NDC: 68180-339-09 (90's)**

Lot Number	Exp. Date	Lot Number	Exp. Date	Lot Number	Exp. Date
G807093	Jul-20	G900231	Nov-20	G907239	Aug-21
G807147	Jul-20	G900232	Nov-20	G907255	Aug-21
G807208	Jul-20	G903277	Mar-21	G907256	Aug-21
G807479	Jul-20	G903278	Mar-21	G907263	Aug-21
G807480	Jul-20	G903279	Mar-21	G001802	Jan-22
G807830	Jul-20	G903280	Mar-21	G001804	Jan-22
G807092	Jul-20	G903281	Mar-21	G001803	Jan-22
G809471	Jul-20	G903818	Apr-21	G001805	Jan-22
G808155	Aug-20	G904048	Apr-21	G001806	Jan-22
G808074	Aug-20	G904164	Apr-21	G001807	Jan-22
G808115	Aug-20	G906548	Jul-21	G001808	Jan-22
G808154	Aug-20	G906549	Jul-21	G001809	Jan-22
G900227	Nov-20	G906550	Jul-21	G001801	Jan-22
G900228	Nov-20	G906547	Jul-21	G002563	Feb-22
G900229	Nov-20	G907279	Aug-21	G002564	Feb-22



# Lupin Pharmaceuticals, Inc.

G900230	Nov-20	G907364	Aug-21		
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## Metformin HCl Extended Release Tablets USP, 500mg; NDC: 68180-336-07 (60's)

Lot Number	Exp. Date	Lot Number	Exp. Date	Lot Number	Exp. Date
G808293	Aug-20	G901201	Dec-20	G906914	Jul-21
G808284	Aug-20	G901202	Dec-20	G002135	Jan-22
G808285	Aug-20	G906915	Jul-21	G002849	Feb-22
G808343	Aug-20	G906913	Jul-21		

## Metformin HCl Extended Release Tablets USP, 1000mg; NDC: 68180-337-07 (60's)

Lot Number	Exp. Date	Lot Number	Exp. Date	Lot Number	Exp. Date
G807619	Jul-20	G900061	Oct-20	G901002	Dec-20
G807620	Jul-20	G900062	Oct-20	G901003	Dec-20
G807733	Jul-20	G900106	Oct-20	G903182	Mar-21
G807734	Jul-20	G900140	Oct-20	G903183	Mar-21
G807735	Jul-20	G900141	Oct-20	G903236	Mar-21
G807445	Jul-20	G900152	Oct-20	G903237	Mar-21
G807617	Jul-20	G809596	Oct-20	G903238	Mar-21
G807618	Jul-20	G809598	Oct-20	G903155	Mar-21
G808042	Jul-20	G810182	Oct-20	G903156	Mar-21
G808043	Jul-20	G810183	Oct-20	G903157	Mar-21
G807349	Jul-20	G810184	Oct-20	G903158	Mar-21
G807350	Jul-20	G810185	Oct-20	G903159	Mar-21
G807444	Jul-20	G810186	Oct-20	G903178	Mar-21
G807507	Jul-20	G810187	Oct-20	G903179	Mar-21
G807508	Jul-20	G810188	Oct-20	G903180	Mar-21
G807314	Jul-20	G810189	Oct-20	G903181	Mar-21
G807316	Jul-20	G809554	Oct-20	G903239	Mar-21
G807325	Jul-20	G809556	Oct-20	G001837	Jan-22
G807348	Jul-20	G809557	Oct-20	G001860	Jan-22
G807616	Jul-20	G809558	Oct-20	G001861	Jan-22
G807312	Jul-20	G809559	Oct-20	G001905	Jan-22
G807313	Jul-20	G809548	Oct-20	G001933	Jan-22
G807315	Jul-20	G809549	Oct-20	G001934	Jan-22
G808374	Aug-20	G809550	Oct-20	G001763	Jan-22
G808427	Aug-20	G809551	Oct-20	G001764	Jan-22
G808373	Aug-20	G809552	Oct-20	G001765	Jan-22
G808426	Aug-20	G809553	Oct-20	G001766	Jan-22
G900057	Oct-20	G809555	Oct-20	G001767	Jan-22
G900058	Oct-20	G901004	Dec-20	G001795	Jan-22
G900059	Oct-20	G901005	Dec-20	G001836	Jan-22
G900060	Oct-20	G901053	Dec-20		



# Lupin Pharmaceuticals, Inc.

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 above lots. 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. Lupin Pharmaceuticals, Inc. is recalling this product from wholesalers, retailers and consumers/users in the United States.

This recall is being made with the knowledge of the Food and Drug Administration.

**Immediately examine your product to determine if you have the recalled lots.**

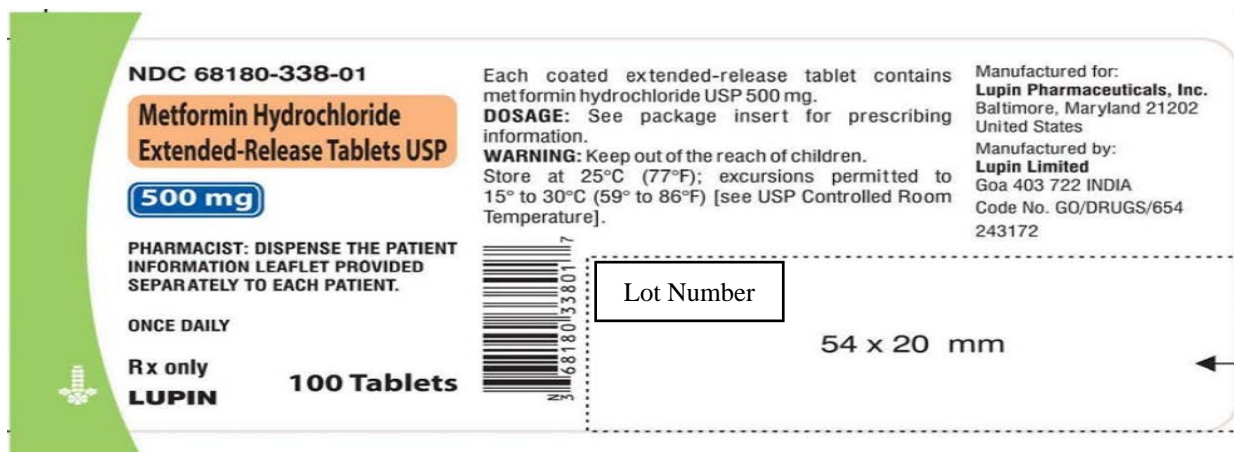
1. If you have a product from recalled lots, DO NOT discard your product. It must be returned to Lupin Pharmaceuticals, Inc. for proper disposal and reimbursement of your out of pocket expense.
2. Contact Inmar Rx Inc. Monday – Friday 9:00 am to 5:00 pm EST at (855) 532-1856 to request a product return and reimbursement packet.
3. Following the instruction provided in the return packet, return the recalled product and pharmacy receipt using the prepaid FedEx Authorized Return Service Shipping label to the address below:

**Inmar Rx Solutions, Inc.  
635 Vine St, Winston Salem, NC 27101**

4. Do not include other Lupin Pharmaceuticals, Inc. labelled items in your return shipment.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

The lot number is printed on the side of the bottle label as indicated below.





# Lupin Pharmaceuticals, Inc.

**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**

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

90 Tablets

Lot Number

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**

**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.

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**Lupin Pharmaceuticals, Inc.**  
Baltimore, Maryland 21202  
United States  
Manufactured by:  
**Lupin Limited**  
Goa 403 722 INDIA  
Code No. GO/DRUGS/654

248067

60 Tablets

Lot Number

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**

**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.

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Code No. GO/DRUGS/654

248068

60 Tablets

Lot Number

70 x 25 mm

Sincerely,

Anurag Mishra