



October 14, 2021

BSE Limited
Department of Corporate Services,
P. J. Towers,
Dalal Street,
MUMBAI - 400 001.

✓ **National Stock Exchange of India Limited**
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051.

Dear Sir/Madam,

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

Enclosed is a Press Release as regards voluntary nationwide recalling of all batches of Irbesartan Tablets and Irbesartan and Hydrochlorothiazide Tablets in the US.

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

Thanking you,

Yours faithfully,
For LUPIN LIMITED

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



LUPIN LIMITED

Registered Office: 3rd Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. Tel : (91-22) 6640 2323.
Corporate Identity Number: L24100MH1983PLC029442

www.lupin.com



Lupin Pharmaceuticals, Inc. Issues Voluntarily Nationwide Recall of all Irbesartan Tablets and Irbesartan and Hydrochlorothiazide Tablets due to potential presence of N-nitrosoirbesartan Impurity

Company Contact:
Shweta Munjal
Email: shwetamunjal@lupin.com

FOR IMMEDIATE RELEASE

Baltimore, Maryland, October 14, 2021: Lupin Pharmaceuticals Inc. is voluntarily recalling the below-mentioned batches of Irbesartan Tablets and Irbesartan and Hydrochlorothiazide Tablets to the consumer level. As part of Lupin's ongoing assessment, analysis revealed that certain tested API batches (but not finished product batches) were above the specification limit for the impurity, N-nitrosoirbesartan. Although Lupin has received no reports of illness that appear to relate to this issue, the company, out of an abundance of caution, is recalling all batches of Irbesartan Tablets USP 75mg, 150mg and 300mg and Irbesartan and Hydrochlorothiazide Tablets USP, 150mg/12.5mg and 300mg/12.5mg in the US.

Lupin discontinued the marketing of Irbesartan and Irbesartan and HCTZ tabs in Jan 2021.

Risk Statement: N-nitrosoirbesartan impurity is a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

From October 8, 2018 (the earliest date of shipment from the manufacturing site of any of the affected batches), to September 30, 2021, Lupin received 4 reports of illness from Irbesartan and 0 reports from Irbesartan and Hydrochlorothiazide.

Irbesartan tablet USP is an angiotensin II receptor blocker indicated for treatment of hypertension, to lower blood pressure, diabetic nephropathy in hypertensive patients with type 2 diabetes, an elevated serum creatinine, and proteinuria. Irbesartan Tablets USP 75mg, 150mg and 300mg is packaged in 30 and 90 count bottles and was distributed nationwide in the US to wholesalers, drug chains, mail order pharmacies and supermarkets. Lupin discontinued the marketing of Irbesartan Tablets on Jan 7, 2021. The recalled lots are included in the table below:

| Product | Lot No | NDC | Distribution Dates |
|------------------------------|--|---------------------|--------------------|
| Irbesartan Tablets USP, 75mg | H000843, H805727, H901579 | 68180-410-06 (30's) | 10/20/2018 |
| | H000844, H000964, H804311, H805267, H805268, H805269 | 68180-410-09 (90's) | - 12/03/2020 |



LUPIN
PHARMACEUTICALS, INC.

| Product | Lot No | NDC | Distribution Dates |
|-------------------------------|--|---------------------|--------------------|
| | H805725, H805726, H901497, H901577, H901578, H902258 | | |
| Irbesartan Tablets USP, 150mg | H804403, H805251, H805640, H901580 | 68180-411-06 (30's) | |
| | H804492, H805252, H805253, H805641, H805642, H805643, H901581, H902139, H902140 | 68180-411-09 (90's) | |
| Irbesartan Tablets USP, 300mg | H804310, H900050, H902262 | 68180-412-06 (30's) | |
| | H000845, H000846, H000965, H805345, H805346, H805347, H805724, H900061, H900062, H900445, H901489, H901490, H901491, H902261 | 68180-412-09 (90's) | |

Irbesartan and hydrochlorothiazide tablet USP is a combination of irbesartan, an angiotensin II receptor antagonist, and hydrochlorothiazide, a thiazide diuretic, indicated for hypertension in patients not adequately controlled with monotherapy or as an initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Irbesartan and hydrochlorothiazide tablet USP, 150mg/12.5mg and 300mg/12.5mg is packaged in 30 and 90 count bottles and was distributed nationwide in the US to wholesalers, drug chains, mail order pharmacies and supermarkets. Lupin discontinued the marketing of Irbesartan and HCTZ Tablets on Jan 7, 2021. The recalled lots are included in the table below:

| Product | Lot No | NDC | Distribution Dates |
|--|--|---------------------|-------------------------------|
| Irbesartan and Hydrochlorothiazide Tablets USP, 150mg/12.5mg | H804537, H805148, H900063, H900522, H901582 | 68180-413-06 (30's) | 10/17/2018 - 11/18/2020 |
| | H000963, H804507, H804536, H805070, H805149, H900064, H900523, H901583, H902530 | 68180-413-09 (90's) | |
| Irbesartan and Hydrochlorothiazide Tablets USP, 300mg/12.5mg | H804192, H805348, H900065, H902264 | 68180-414-06 (30's) | |
| | H804082, H804121, H804338, H804538, H804539, H805349, H805350, H900066, H900067, H902265, H902275, H902276, H902531, H902532 | 68180-414-09 (90's) | |



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

Patients taking, Irbesartan Tablets USP, 75mg, 150mg and 300mg and Irbesartan and Hydrochlorothiazide Tablets USP, 150mg/12.5mg and 300mg/12.5mg are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment.

Wholesalers, distributors and retailers that have Irbesartan Tablets USP, 75mg, 150mg and 300mg and Irbesartan and Hydrochlorothiazide Tablets USP, 150mg/12.5mg and 300mg/12.5mg that are being recalled should discontinue distribution of the recalled product lots immediately and return it to Inmar Rx Solutions, Inc., 635 Vine St, Winston Salem, NC 27101. Tel: (855) 769-3988 / (855) 769-3989.

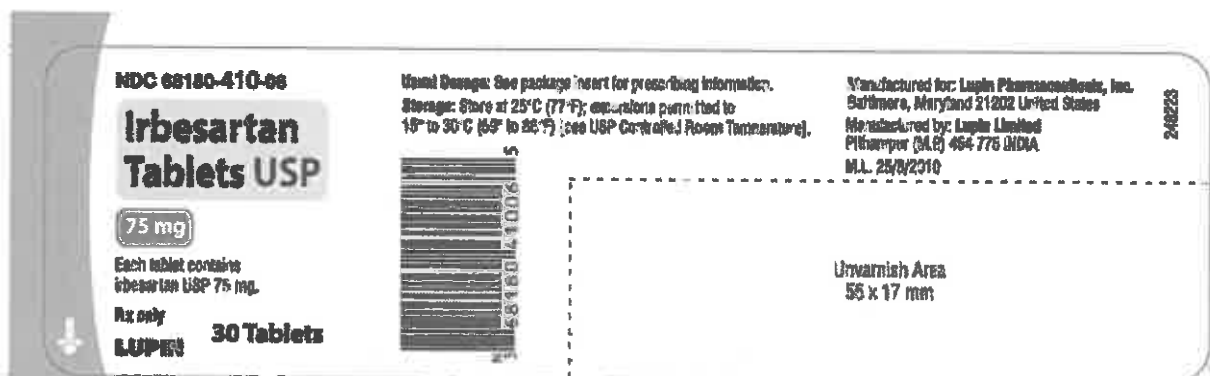
Consumers, wholesalers, distributors, and retailers with questions regarding this recall should contact Inmar Rx Solutions, Inc. at (855) 769-3988 / (855) 769-3989 Monday – Friday 09:00 am to 05:00 pm EST. For reimbursement, please have the recalled lots returned to Inmar Rx Solutions, Inc.; the lot number can be found on the side 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:





LUPIN
PHARMACEUTICALS, INC.

NDC 68180-410-09

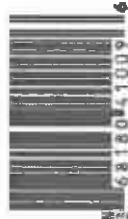
**Irbesartan
Tablets USP**

75 mg

Each tablet contains
Irbesartan USP 75 mg.

Rx only
LUPIN 90 Tablets

Usual Dosage: See package insert for prescribing information.
Storage: 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
Pitampur (M.E) 454 775 INDIA
M.L. 25/8/2010

248224

Unvarnish Area
55 x 17 mm

NDC 68180-411-08

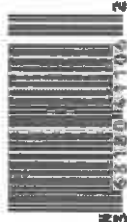
**Irbesartan
Tablets USP**

150 mg

Each tablet contains
Irbesartan USP 150 mg.

Rx only
LUPIN 30 Tablets

Usual Dosage: See package insert for prescribing information.
Storage: 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
Pitampur (M.E) 454 775 INDIA
M.L. 25/8/2010

248225

Unvarnish Area
55 x 17 mm

NDC 68180-411-09

**Irbesartan
Tablets USP**

150 mg

Each tablet contains
Irbesartan USP 150 mg.

Rx only
LUPIN 90 Tablets

Usual Dosage: See package insert for prescribing information.

Storage: 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
Pitampur (M.E) 454 775
INDIA
M.L. 25/8/2010

248226

Unvarnish Area
54 x 20 mm



LUPIN
PHARMACEUTICALS, INC.

NDC 68180-412-08

**Irbesartan
Tablets USP**

300 mg

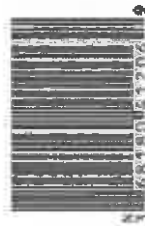
Each tablet contains
irbesartan USP 300 mg.

Rx only
LUPIN

30 Tablets

Usual Dosage: See package insert
for prescribing information.

Storage: 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
Pithampur (M.R.) 454 775
INDIA
M.L. 25/8/2010

248228

Unvarnish Area
54 x 17 mm

NDC 68180-412-09

**Irbesartan
Tablets USP**

300 mg

Each tablet contains
irbesartan USP 300 mg.

Rx only
LUPIN

90 Tablets

Usual Dosage: See package insert
for prescribing information.

Storage: 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
Pithampur (M.R.) 454 775
INDIA
M.L. 25/8/2010

248229

Unvarnish Area
75 x 19 mm

NDC 68180-413-06

**Irbesartan and
Hydrochlorothiazide
Tablets USP**

150 mg / 12.5 mg

Each film-coated tablet contains:
Irbesartan USP 150 mg
Hydrochlorothiazide USP 12.5 mg

Rx only
LUPIN

30 Tablets

Usual Dosage: See package insert for prescribing
information.

Storage: Store at 25°C (77°F); excursions permitted to 15° to
30°C (59° to 86°F) [see USP Controlled Room Temperature].
M.L. 25/8/2010



Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202 United States
Manufactured by:
Lupin Limited
Pithampur (M.R.) 454 775, INDIA

248046

54 x 16 mm



LUPIN
PHARMACEUTICALS, INC.

NDC 68180-413-09

**Irbesartan and
Hydrochlorothiazide
Tablets USP**

150 mg/12.5 mg

Each film-coated tablet contains:
Irbesartan USP 150 mg
Hydrochlorothiazide USP 12.5 mg

Rx only

LUPIN

90 Tablets

Usual Dosage: See package insert for prescribing information.

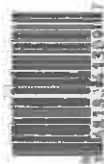
Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature).

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

Manufactured by:
Lupin Limited
Pitampur (M.P.) 464 775,
INDIA

M.L. 25/8/2010

248044



54 x 16 mm

NDC 68180-414-06

**Irbesartan and
Hydrochlorothiazide
Tablets USP**

300 mg/12.5 mg

Each film-coated tablet contains:
Irbesartan USP 300 mg
Hydrochlorothiazide USP 12.5 mg

Rx only

LUPIN

30 Tablets

Usual Dosage: See package insert for prescribing information.

Storage: 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
Pitampur (M.P.) 464 775, INDIA

M.L. 25/8/2010

248045



54 x 16 mm



LUPIN
PHARMACEUTICALS, INC.

NDC 68180-414-09

Irbesartan and Hydrochlorothiazide Tablets USP

300 mg/12.5 mg

Each film-coated tablet contains:
Irbesartan USP 300 mg
Hydrochlorothiazide USP 12.5 mg

Rx only

LUPIN

90 Tablets

Usual Dosage: See package insert for prescribing information.
Storage: 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
Pithampur (M.P.) 454 775, INDIA
M.L. 25/8/2010

68180-414-09

300mg

60 x 18 mm

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.

© 2020 Lupin Pharmaceuticals, Inc. All rights reserved.