DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Lupin Pharmaceuticals, Inc. Issues Voluntarily Nationwide Recall of All Irbesartan Tablets and Irbesartan and Hydrochlorothiazide Tablets Due to Potential Presence of N-nitrosoirbesartan Impurity

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 – 12/03/2020
	H000844, H000964, H804311, H805267, H805268, H805269, H805725, H805726, H901497, H901577, H901578, H902258	68180-410-09 (90's	

Product	Lot No	NDC	Distribution Dates
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
- Regular Mail or Fax: Download form 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

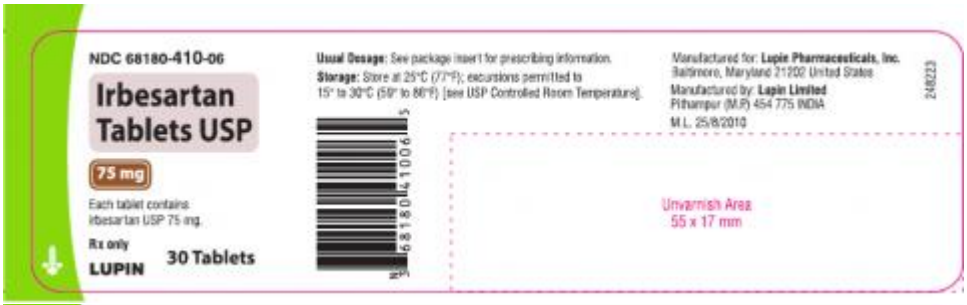
Consumers:

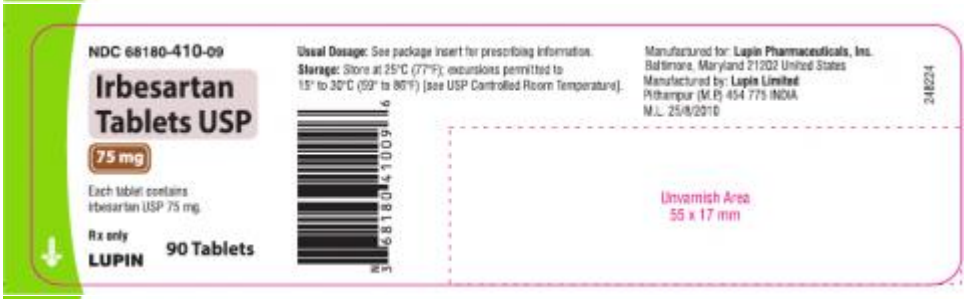
Inmar Rx Solutions, Inc.
(855) 769-3988 / (855) 769-3989

Media:

Shweta Munjal
shwetamunjal@lupin.com

Product Photos

- 

- 

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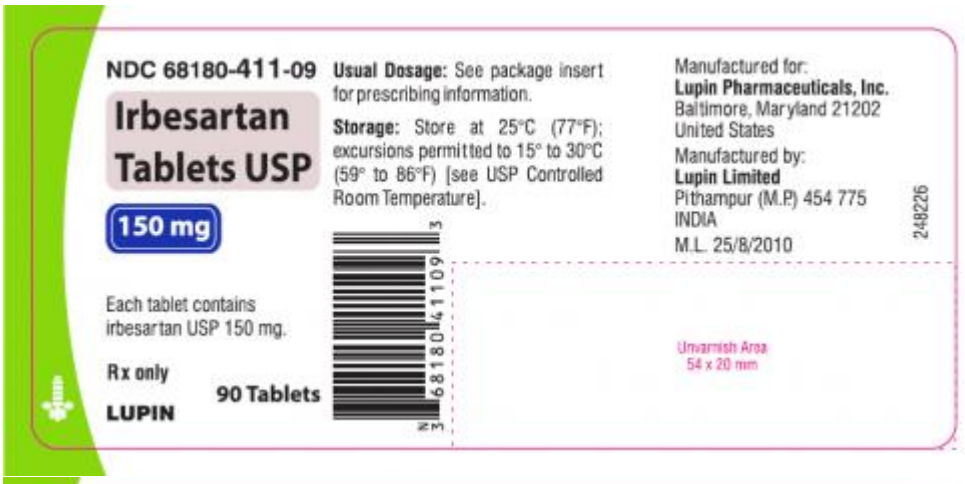
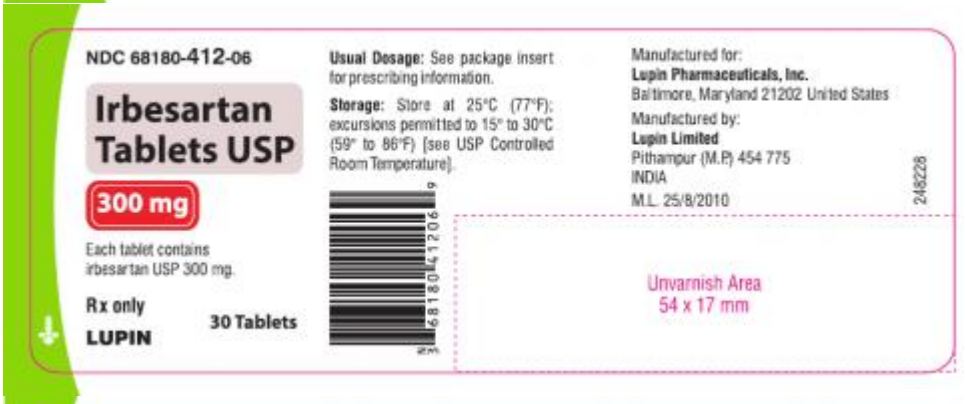
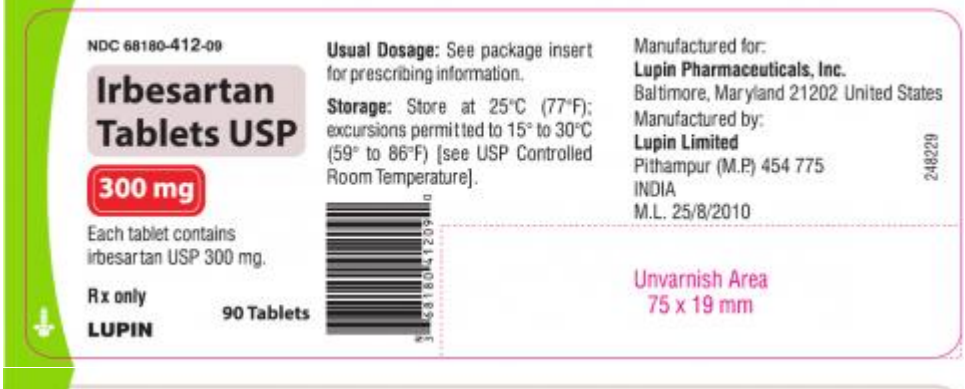
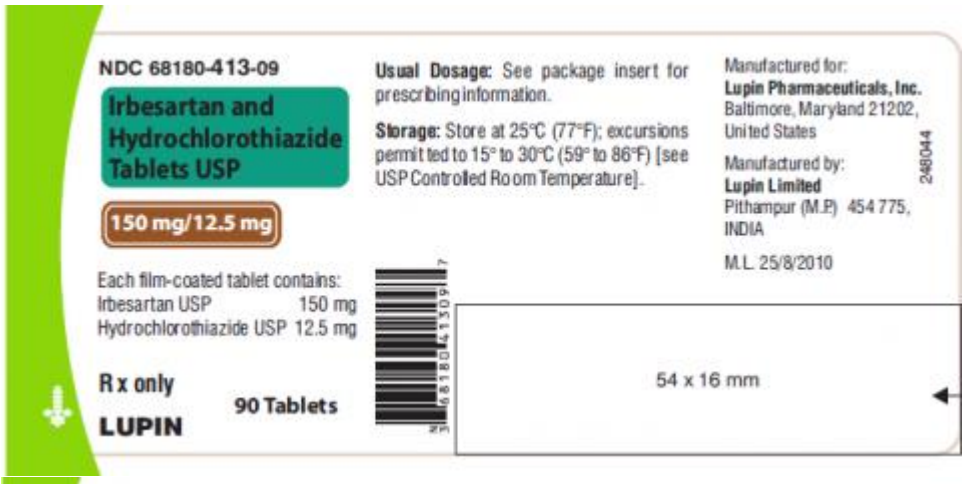
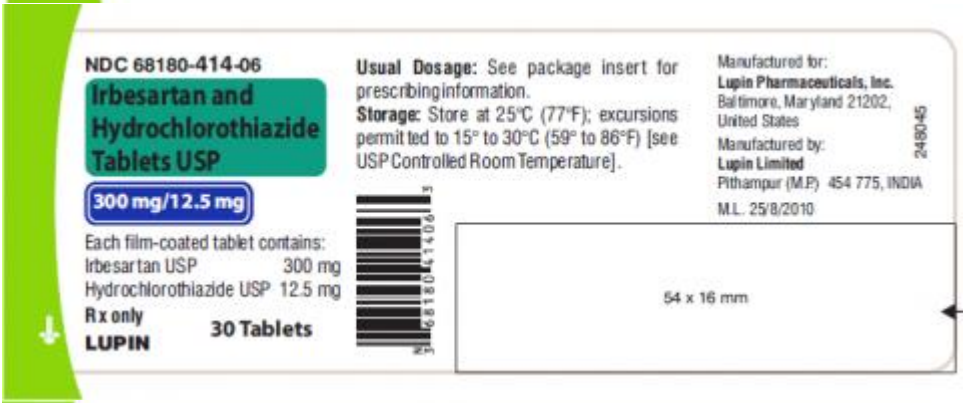

NDC 68180-411-09
Irbesartan Tablets USP
150 mg
Each tablet contains irbesartan USP 150 mg.
Rx only
LUPIN
90 Tablets
Usual Dosage: See package insert for prescribing information.
Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States
Manufactured by:
Lupin Limited
Pithampur (M.P) 454 775
INDIA
M.L. 25/8/2010
248226
Unvarnish Area
54 x 20 mm

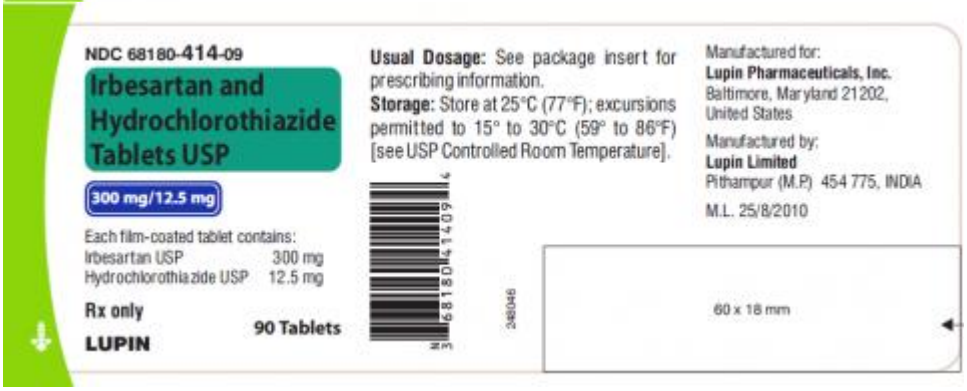

NDC 68180-412-06
Irbesartan Tablets USP
300 mg
Each tablet contains irbesartan USP 300 mg.
Rx only
LUPIN
30 Tablets
Usual Dosage: See package insert for prescribing information.
Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202 United States
Manufactured by:
Lupin Limited
Pithampur (M.P) 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.P) 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°F 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.P) 454 775, INDIA
248043
54 x 16 mm

- 

- 

- 

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-all-irbesartan-tablets-and-irbesartan