GOVERNMENT OF THE UNITED STATES
VIRGIN ISLANDS
DEPARTMENT OF HEALTH
DIVISION OF ENVIRONMENTAL HEALTH

3500 ESTATE RICHMOND
ST. CROIX, VI 00820
(340) 718-1311 X 3709

1303 HOSPITAL GROUND, SUITE 10
ST. THOMAS, VI 00920
(340) 774-9000 X 4642

DOH Notifies the Public of Recalled Two Blood Pressure Drugs

FOR IMMEDIATE RELEASE
Contact: Rebekah Kubla

US Virgin Islands, 11/05/2021 - The Department of Health (DOH) notifies the public that on October 14, 2021, Lupin Pharmaceuticals Inc. voluntarily recalled batches two blood pressure drugs. The recall is due to the potential presence of a probable human carcinogen based on results from laboratory tests (N-nitrosoirbesartan impurity, a substance that could cause cancer). Photos of the recalled drug labels are below. Images of the product packaging can be found at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-all-irbesartan-tablets-and-irbesartan#recall-announcement.

Lupin has received no reports of illness that appear to relate to this issue but 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 out of an abundance of caution,

Lupin advises patients who are prescribed the drugs to continue taking their medication and contact their pharmacist, physician, or medical provider for advice "regarding an alternative treatment."

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 this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax.

- Complete and submit the report https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

- Regular Mail or Fax: https://www.fda.gov/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

For an ongoing list of FDA recall information, visit https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

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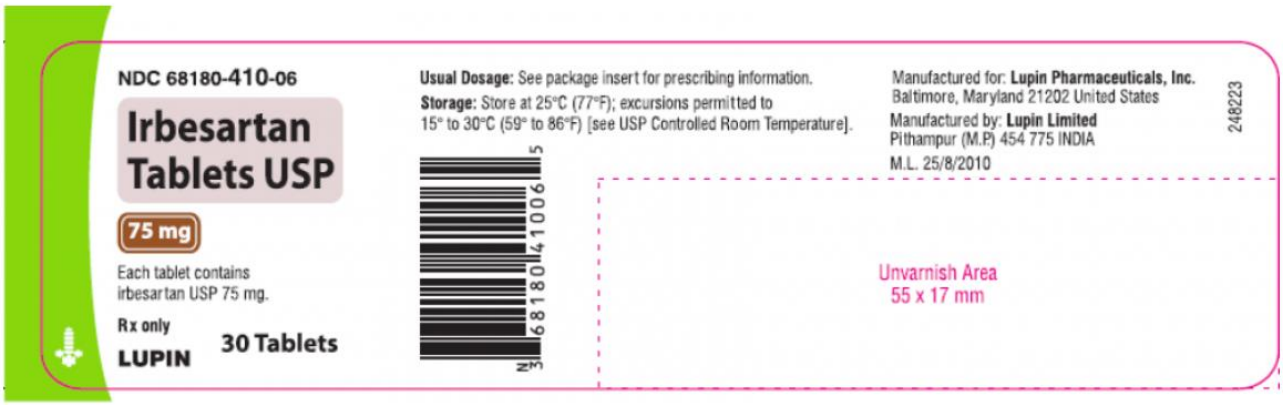
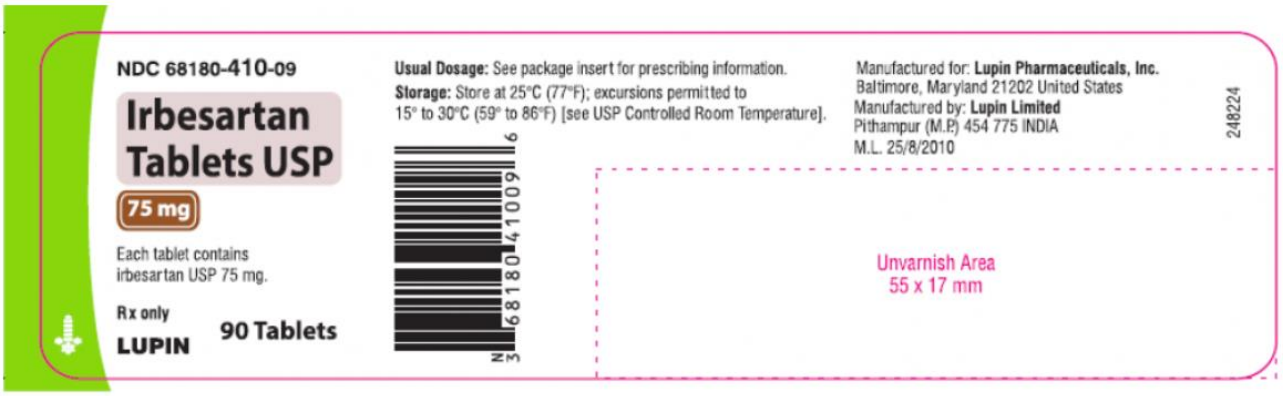
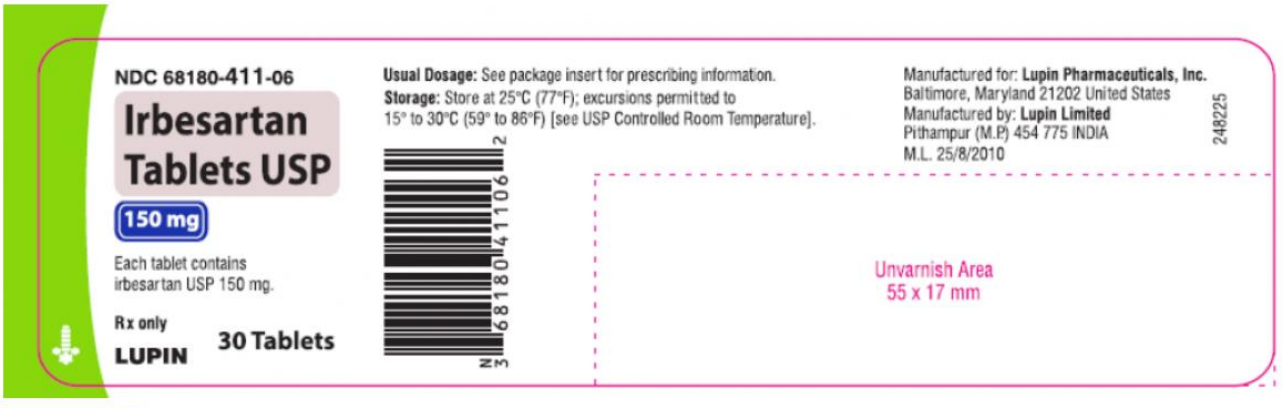
Product Photos







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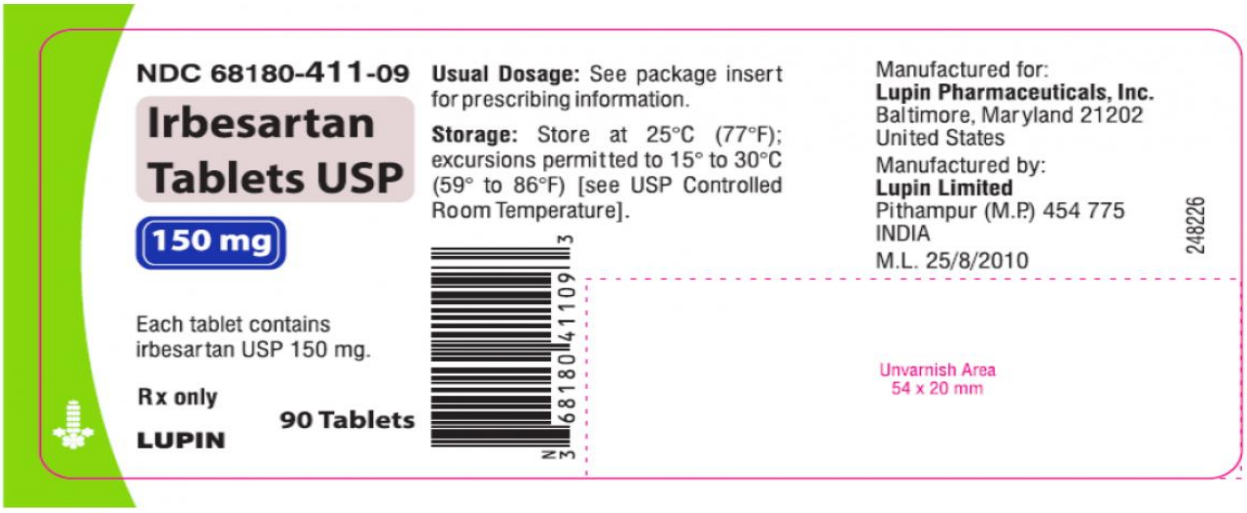

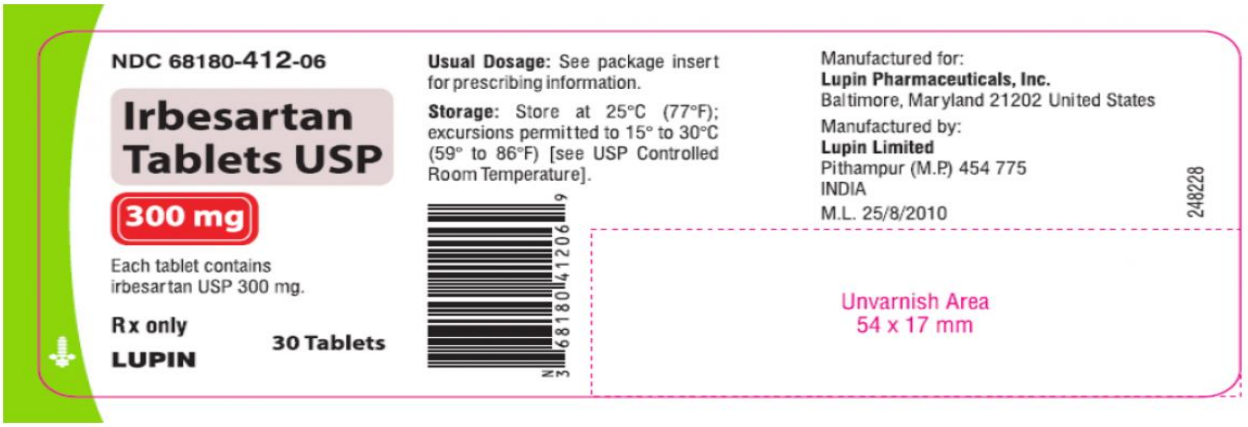

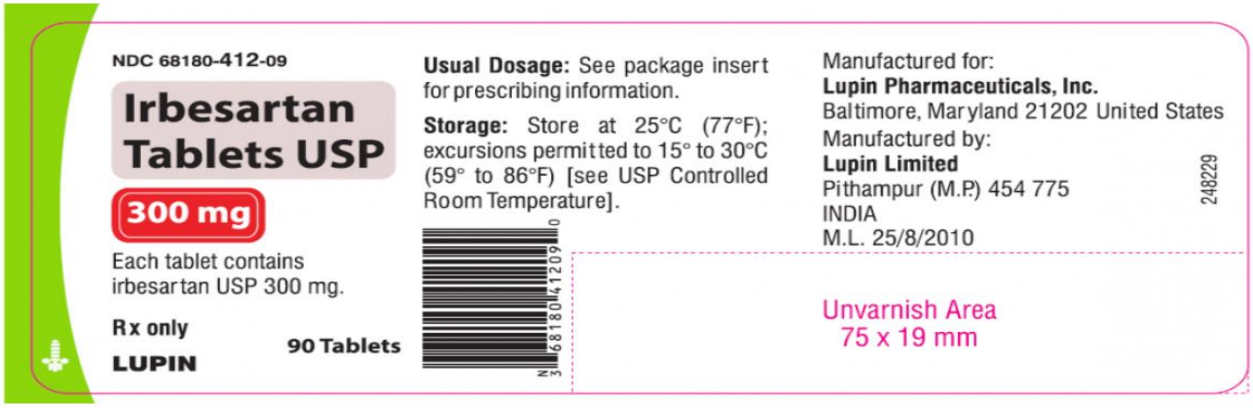

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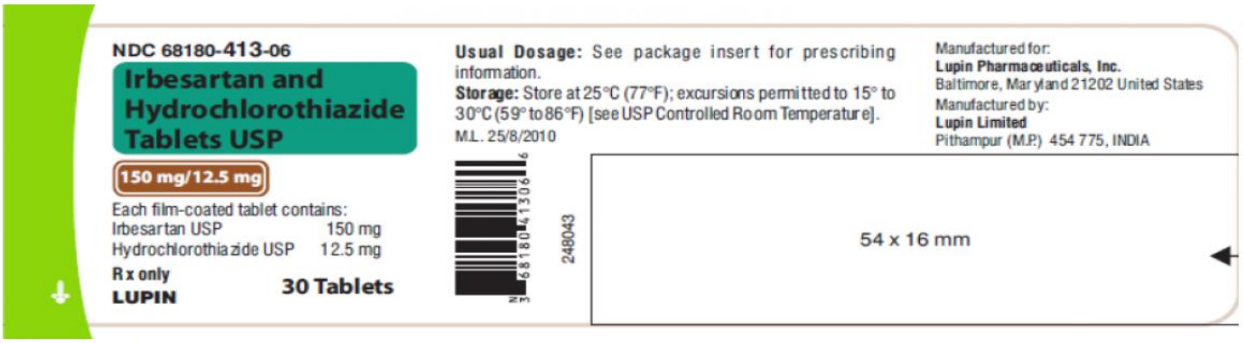

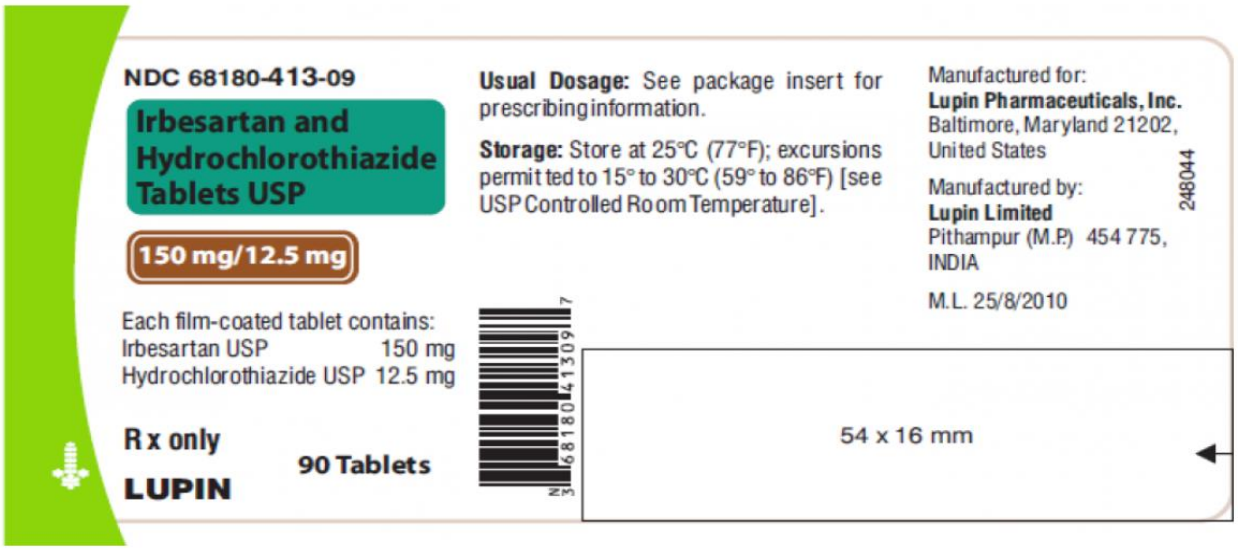

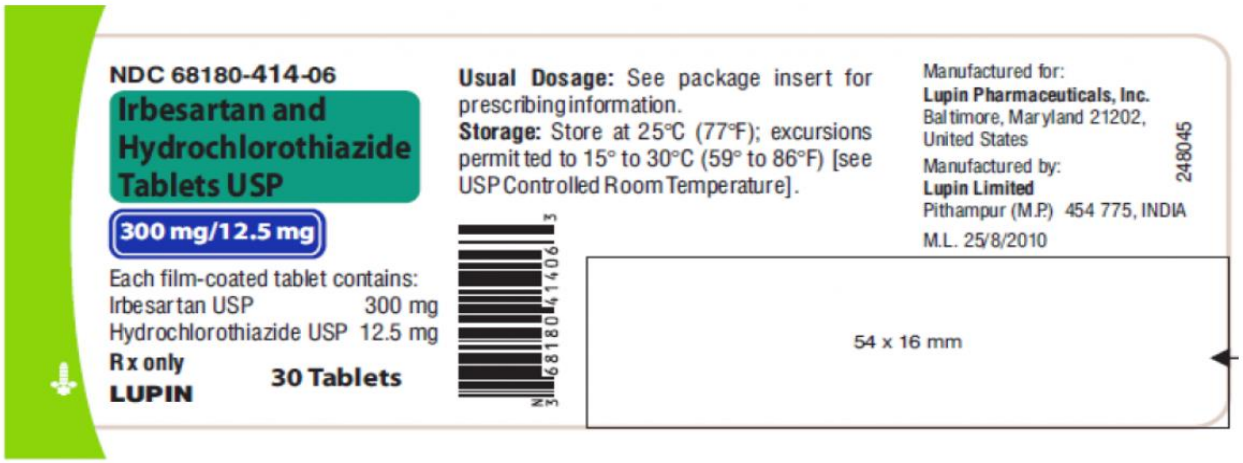

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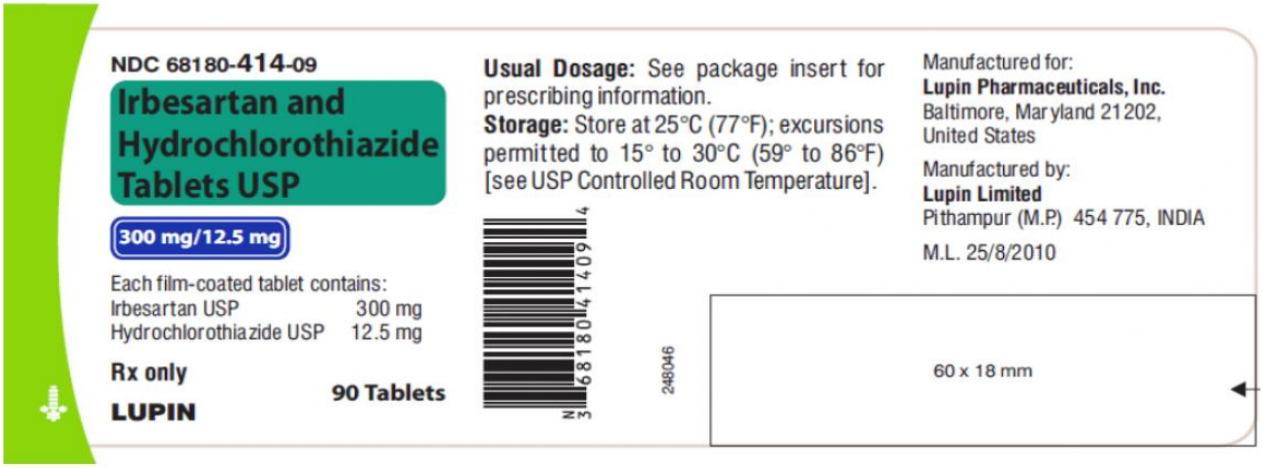

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