Company Announcement

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.

Teva Pharmaceuticals USA Issues Voluntary Nationwide Recall of All Amlodipine/Valsartan Combination Tablets and Amlodipine/Valsartan/Hydrochlorothiazide Combination Tablets That Are Within Expiry

For Immediate Release

November 27, 2018

Contact

Consumers

Teva's Medical Information
druginfo@tevapharm.com (mailto: druginfo@tevapharm.com)
888-838-2872

Announcement

View Product Photos

Teva Pharmaceuticals has initiated a voluntary recall in the United States, to the patient level, of all lots of Amlodipine / Valsartan combination tablets and Amlodipine / Valsartan / Hydrochlorothiazide combination tablets (see table below) due to an impurity detected above specification limits in an active pharmaceutical ingredient (API)

manufactured by Mylan India. The impurity found in Mylan's valsartan API is known as N-nitroso-diethylamine (NDEA), which has been classified as a probable human carcinogen. This chemical is typically found in very small amounts in certain foods, drinking water, air pollution, and certain industrial processes.

Amlodipine/Valsartan combination tablets and Amlodipine/Valsartan/Hydrochlorothiazide combination tablets are used for the treatment of high blood pressure. To date, Teva has not received any reports of adverse events signaling a potential link or exposure to valsartan.

Patients taking Amlodipine / Valsartan combination tablets or Amlodipine / Valsartan / Hydrochlorothiazide combination tablets are advised to continue taking their medication and to contact their pharmacist or physician for advice on alternative treatment. The risk of harm to a patient's health may be higher if the treatment is stopped immediately without any comparable alternative treatment.

Teva Pharmaceuticals USA is notifying its distributors and customers by certified mail and is arranging for return/reimbursement of returned recalled products. Distributors and retailers that have product that is being recalled should immediately stop distribution and quarantine any quantities remaining in their control and return the recalled product.

Customers and patients with medical-related questions, information about an Adverse Event or other questions about the Teva products being recalled should contact Teva's Medical Information by phone at: 888-838-2872, option 3, then, option 4. Live calls are received Monday-Friday, 9:00AM-5:00PM Eastern Time with Voicemail available 24 hours/day, 7 days/week or email **druginfo@tevapharm.com (mailto:druginfo@tevapharm.com)**.

Adverse reactions or other problems experienced with the use of the products may also be reported to Teva directly at 888-838-2872 or 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 (http://www.fda.gov/medwatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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

Patient safety and product quality is critical to Teva. As always, Teva will continue to partner with, and regularly update, all relevant stakeholders, including regulatory authorities, to resolve

this situation. This issue is not limited to valsartan medicines manufactured and distributed by Teva. Some valsartan-containing products manufactured and distributed by other pharmaceutical companies using the same API supplier may also be affected.

Lots Under Voluntary Recall

The products that are part of this voluntary recall and listed below are packed in bottles. These lots were distributed nationwide to Teva's Direct Accounts (Wholesale/Distributor/Retail/Repackagers/VA Pharmacy, et. al).

Lot #	Exp. Date	Product Description / Strength	Bottle Size	NDC
23X017	11/2018	Amlodipine and Valsartan Tablets 5 mg/160 mg	90 Count	0093-7690-98
23X018	11/2018	Amlodipine and Valsartan Tablets 5 mg/160 mg	30 Count	0093-7690-56

Lot #	Exp. Date	Product Description / Strength	Bottle Size	NDC
23X018	11/2018	Amlodipine and Valsartan Tablets 5 mg/160 mg	90 Count	0093-7690-98
23X019	11/2018	Amlodipine and Valsartan Tablets 5 mg/160 mg	30 Count	0093-7690-56
23X019	11/2018	Amlodipine and Valsartan Tablets 5 mg/160 mg	90 Count	0093-7690-98
23X020	11/2018	Amlodipine and Valsartan Tablets 5 mg/160 mg	30 Count	0093-7690-56
23X022	4/2019	Amlodipine and Valsartan Tablets 5 mg/160 mg	30 Count	0093-7690-56
23X023	4/2019	Amlodipine and Valsartan Tablets 5 mg/160 mg	30 Count	0093-7690-56
23X023	4/2019	Amlodipine and Valsartan Tablets 5 mg/160 mg	90 Count	0093-7690-98
23X024	4/2019	Amlodipine and Valsartan Tablets 5 mg/160 mg	90 Count	0093-7690-98
24X012	11/2018	Amlodipine and Valsartan Tablets 10 mg/160 mg	30 Count	0093-7691-56
24X012	11/2018	Amlodipine and Valsartan Tablets 10 mg/160 mg	90 Count	0093-7691-98
24X013	11/2018	Amlodipine and Valsartan Tablets 10 mg/160 mg	30 Count	0093-7691-56
25X028	11/2018	Amlodipine and Valsartan Tablets 5 mg/320 mg	90 Count	0093-7692-98
25X029	11/2018	Amlodipine and Valsartan Tablets 5 mg/320 mg	30 Count	0093-7692-56
25X029	11/2018	Amlodipine and Valsartan Tablets 5 mg/320 mg	90 Count	0093-7692-98
25X030	11/2018	Amlodipine and Valsartan Tablets 5 mg/320 mg	30 Count	0093-7692-56
25X031	11/2018	Amlodipine and Valsartan Tablets 5 mg/320 mg	30 Count	0093-7692-56
25X032	11/2018	Amlodipine and Valsartan Tablets 5 mg/320 mg	30 Count	0093-7692-56
25X035	4/2019	Amlodipine and Valsartan Tablets 5 mg/320 mg	30 Count	0093-7692-56
25X037	4/2019	Amlodipine and Valsartan Tablets 5 mg/320 mg	30 Count	0093-7692-56
26X036	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	90 Count	0093-7693-98
26X038	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	90 Count	0093-7693-98
26X039	11/2018	Amlodipine and Valsartan Tablets	30 Count	0093-7693-56

Lot #	Exp. Date	Product Description / Strength	Bottle Size	NDC
		10 mg/320 mg		
26X039	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	90 Count	0093-7693-98
26X040	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56

Lot #	Exp. Date	Product Description / Strength	Bottle Size	NDC
26X041	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X042	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X043	11/2018	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X044	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	90 Count	0093-7693-98
26X045	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	90 Count	0093-7693-98
26X046	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X047	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X048	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X049	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X050	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56
26X051	4/2019	Amlodipine and Valsartan Tablets 10 mg/320 mg	30 Count	0093-7693-56

Lot #	Exp. Date	Product Description/ Strength	Bottle Size	NDC
18X010	2/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg	30 count	0093-7807-56
18X010	2/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg	90 count	0093-7807-98
18X011	2/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg	30 count	0093-7807-56
20X006	11/2018	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/12.5 mg	30 count	0093-7810-56
20X006	11/2018	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/12.5 mg	90 count	0093-7810-98
21X006	11/2018	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/25 mg	30 count	0093-7038-56
21X006	11/2018	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/25 mg	90 count	0093-7038-98
21X007	2/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/25 mg	30 count	0093-7038-56
22X045	2/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg	30 count	0093-7809-56
22X045	2/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg	90 count	0093-7809-98
22X046	02/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg	30 count	0093-7809-56
22X047	02/2019	Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg	30 count	0093-7809-56

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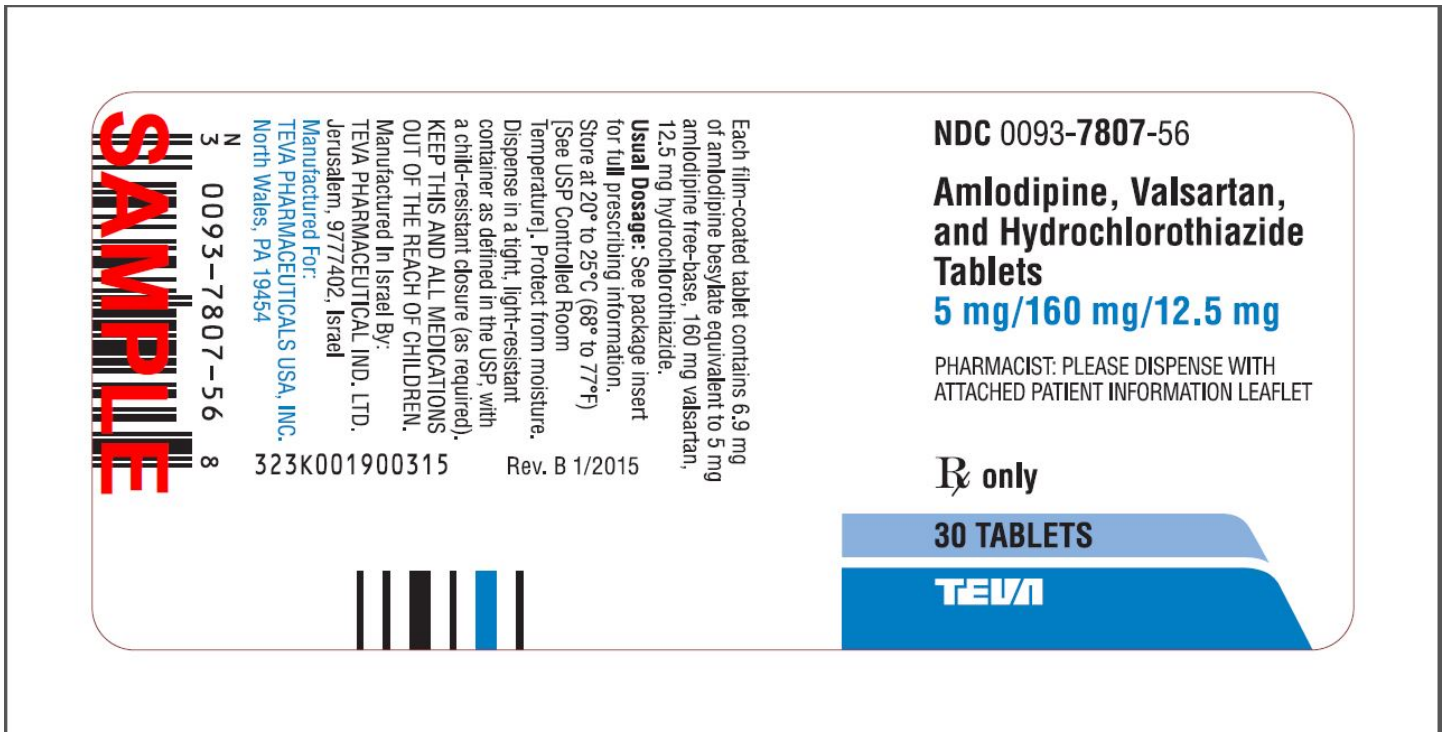
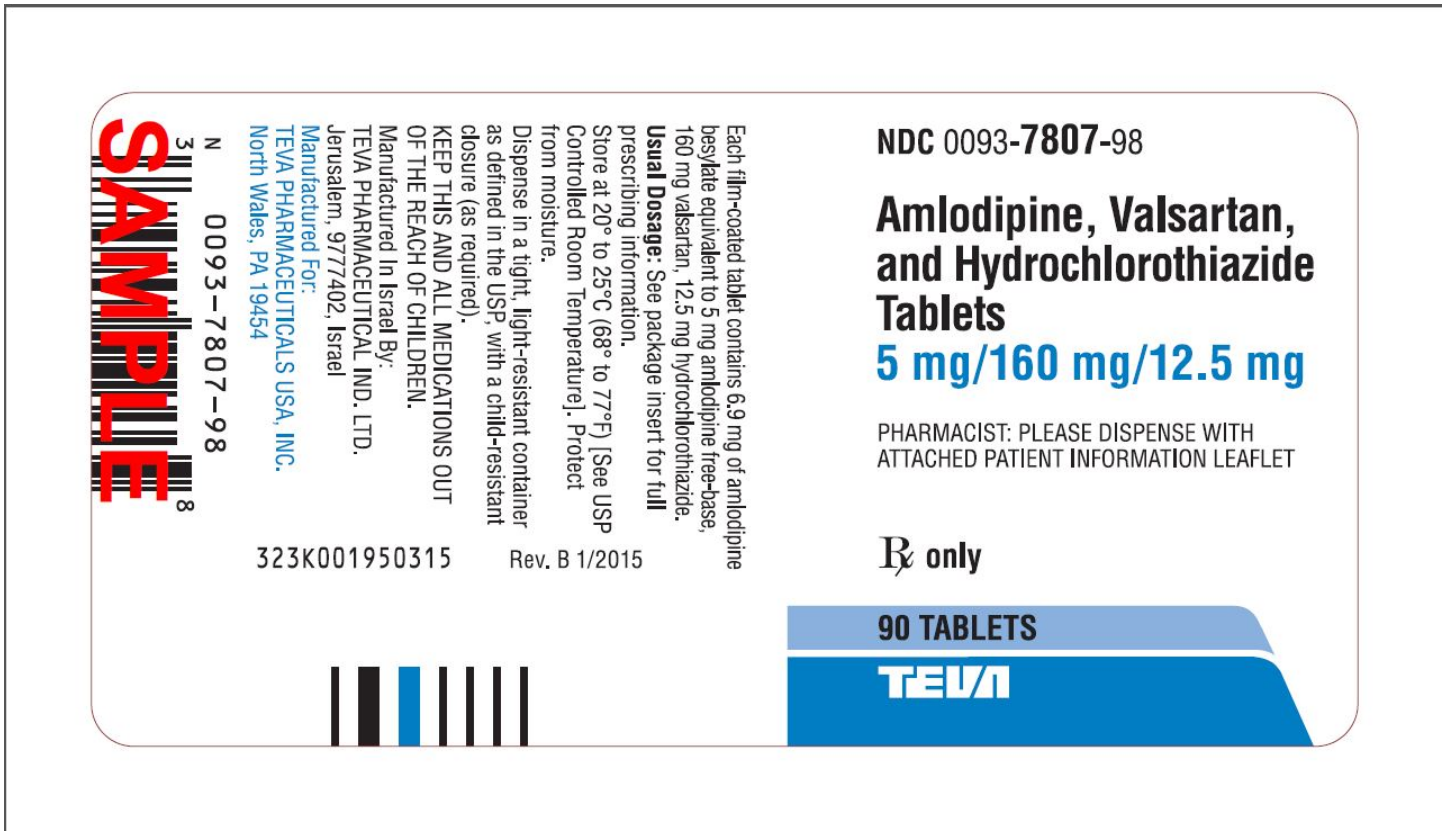
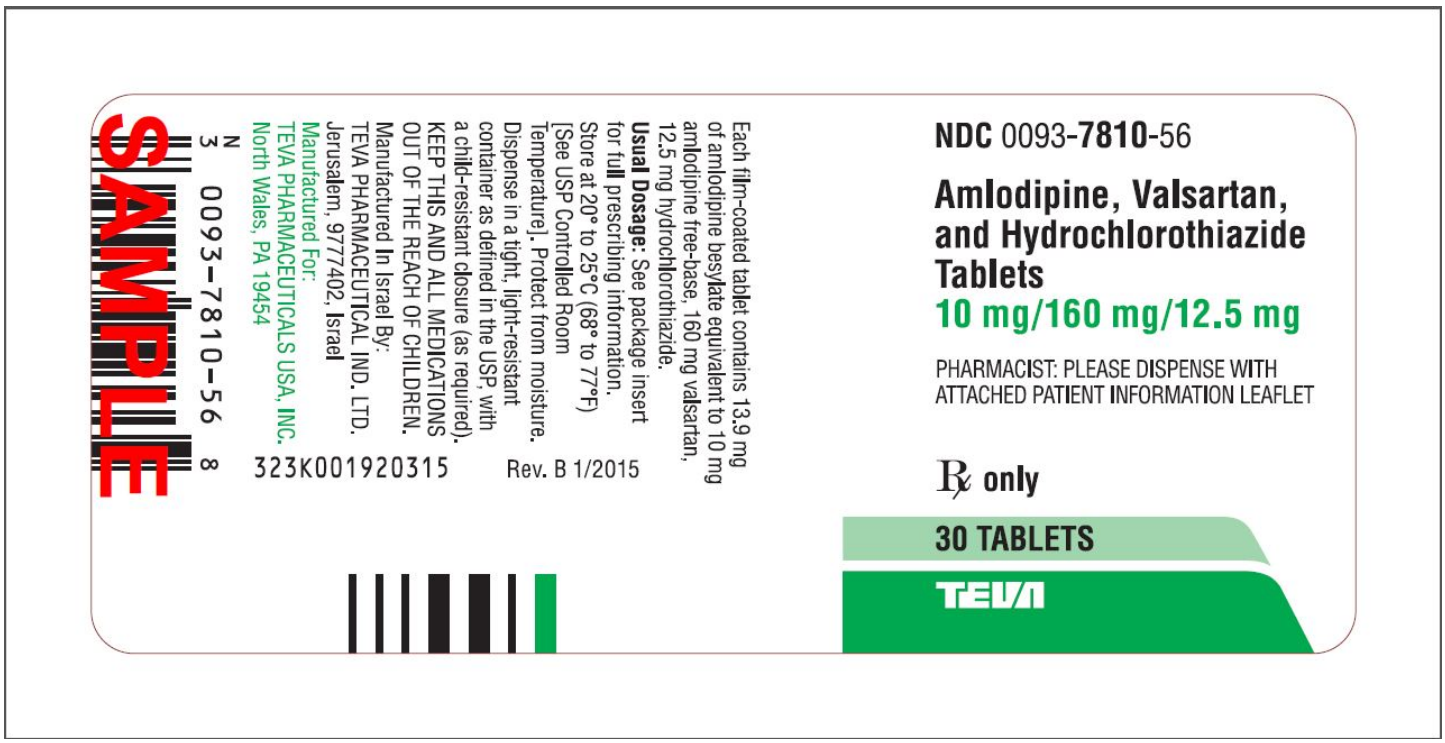
Product Photos




SAMPLE
N 3 0093-7807-98 8
Each film-coated tablet contains 6.9 mg of amlodipine besylate equivalent to 5 mg amlodipine free-base, 160 mg valsartan, 12.5 mg hydrochlorothiazide.
Usual Dosage: See package insert for full prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from moisture.
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Manufactured In Israel By:
TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 9777402, Israel
Manufactured For:
TEVA PHARMACEUTICALS USA, INC.
North Wales, PA 19454
323K001950315
Rev. B 1/2015
NDC 0093-7807-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
5 mg/160 mg/12.5 mg
PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET
℞ only
90 TABLETS
TEVA


SAMPLE
N 3 0093-7810-56 8
Each film-coated tablet contains 13.9 mg of amlodipine besylate equivalent to 10 mg amlodipine free-base, 160 mg valsartan, 12.5 mg hydrochlorothiazide.
Usual Dosage: See package insert for full prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from moisture.
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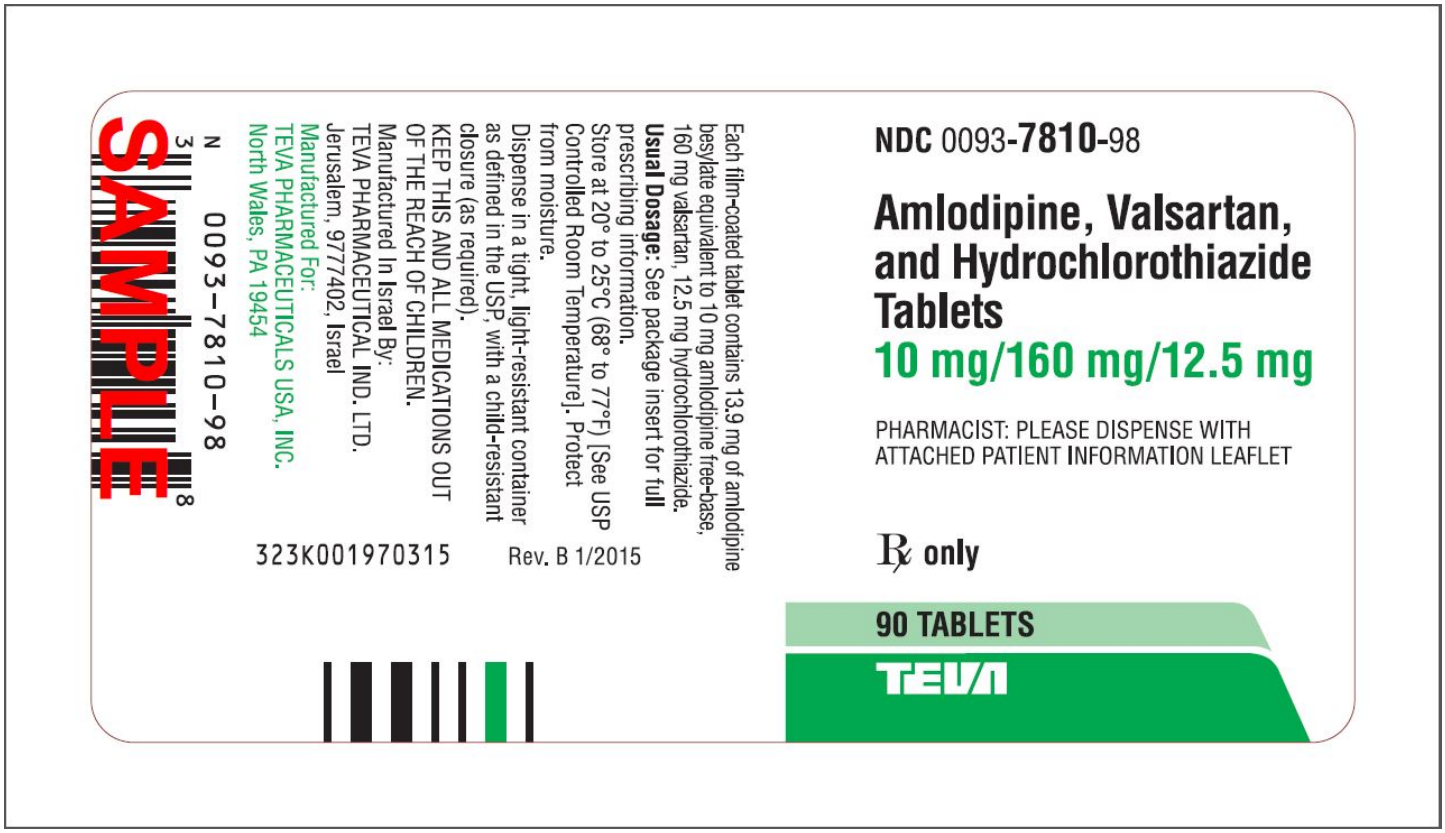
North Wales, PA 19454
323K001920315
Rev. B 1/2015
NDC 0093-7810-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
10 mg/160 mg/12.5 mg
PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET
℞ only
30 TABLETS
TEVA


SAMPLE
N 3 0093-7810-98 8
Each film-coated tablet contains 13.9 mg of amlodipine besylate equivalent to 10 mg amlodipine free-base, 160 mg valsartan, 12.5 mg hydrochlorothiazide.
Usual Dosage: See package insert for full prescribing information.
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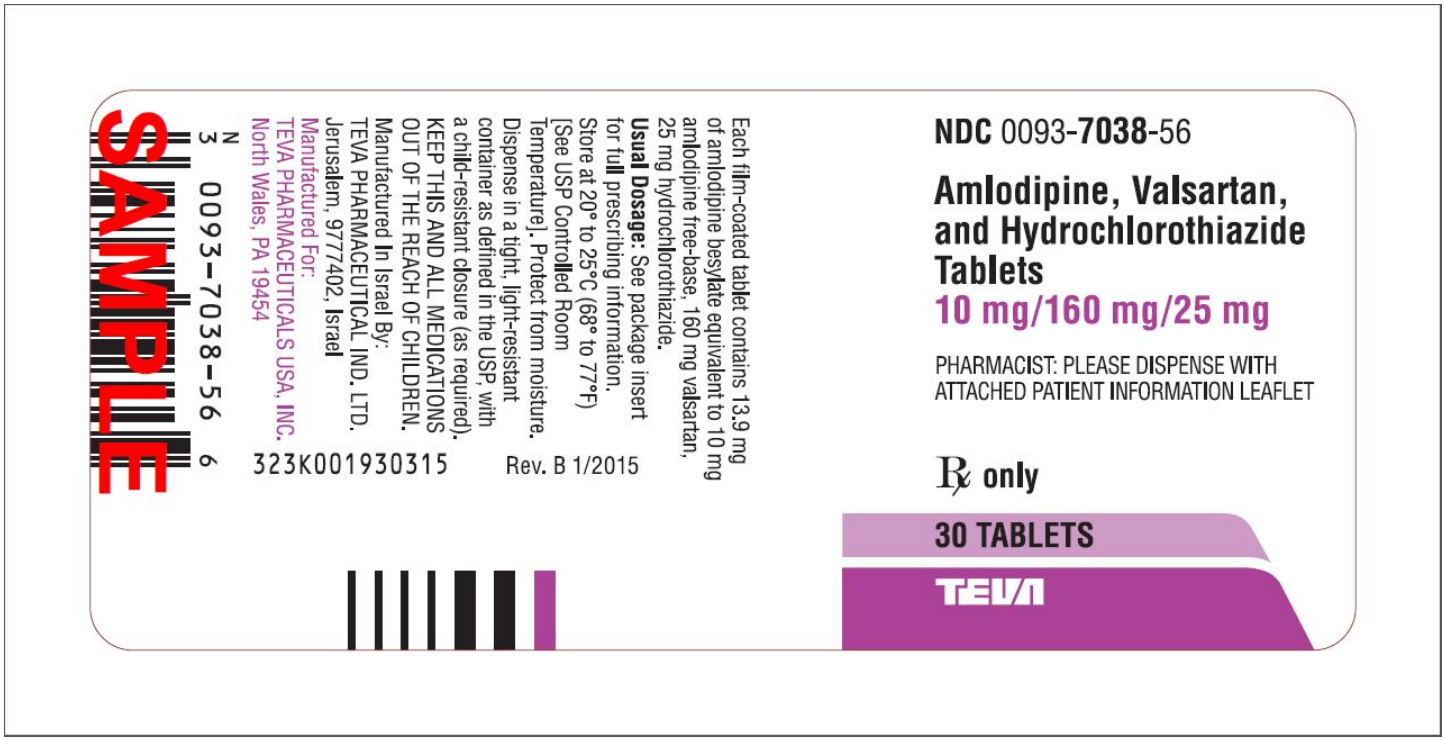
North Wales, PA 19454
323K001970315
Rev. B 1/2015
NDC 0093-7810-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
10 mg/160 mg/12.5 mg
PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET
℞ only
90 TABLETS
TEVA


SAMPLE
N 3 0093-7038-56 6
Each film-coated tablet contains 13.9 mg of amlodipine besylate equivalent to 10 mg amlodipine free-base, 160 mg valsartan, 25 mg hydrochlorothiazide.
Usual Dosage: See package insert for full prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from moisture.
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).
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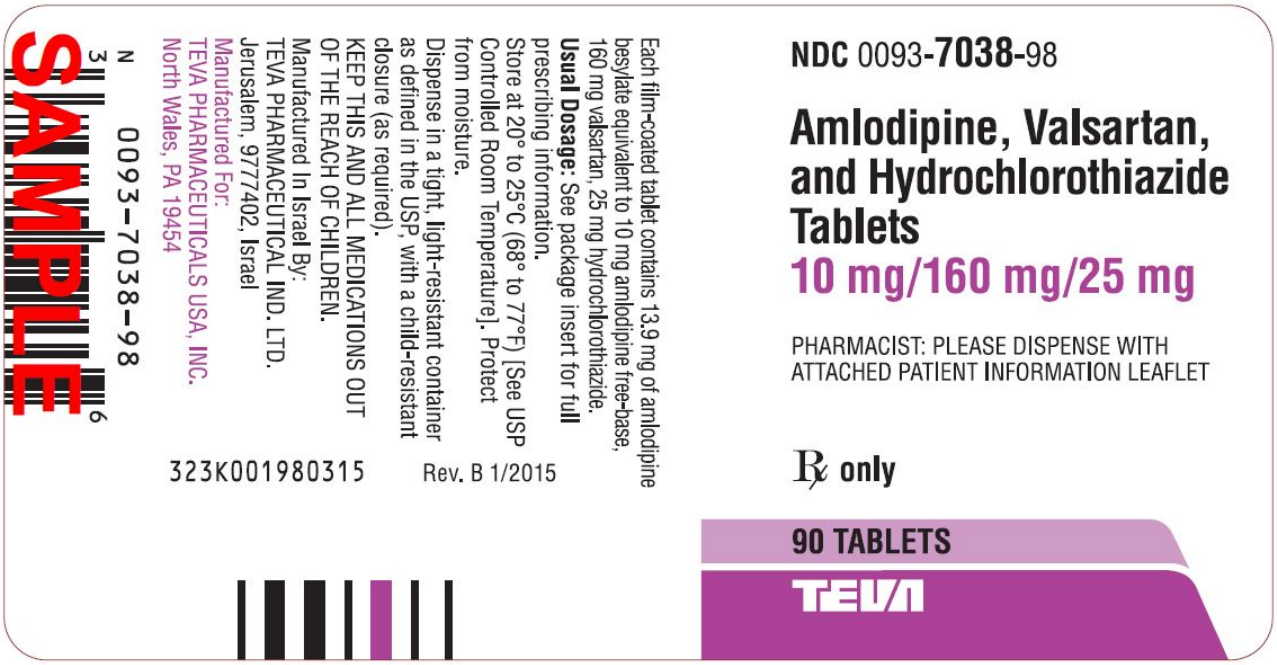
North Wales, PA 19454
323K001930315
Rev. B 1/2015
NDC 0093-7038-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
10 mg/160 mg/25 mg
PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET
℞ only
30 TABLETS
TEVA


NDC 0093-7038-98
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10 mg/160 mg/25 mg
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North Wales, PA 19454
323K001980315
Rev. B 1/2015
N 0093-7038-98
SAMPLE


NDC 0093-7809-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets
10 mg/320 mg/25 mg
PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET
℞ only
90 TABLETS
TEVA
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Usual Dosage: See package insert for full prescribing information.
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323K001990315
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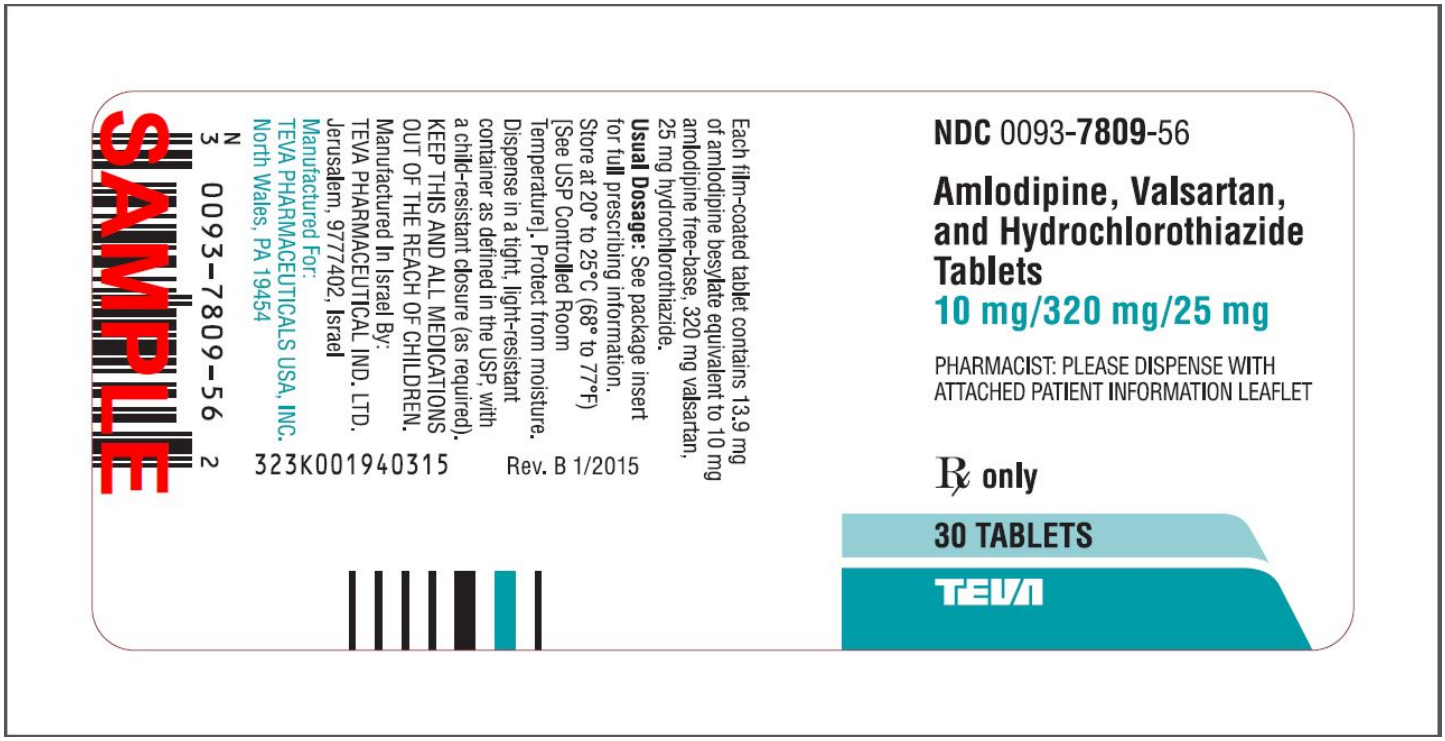
N 0093-7809-98
SAMPLE



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