

Prinston Pharmaceutical Inc Issues Voluntary Nationwide Recall of Valsartan and Valsartan HCTZ Tablets Due to detection of a Trace Amount of Unexpected Impurity, N-nitrosodimethylamine (NDMA) in the Products

Contacts

Consumers: 888-679-5120

Pharmacies, Distributors and Wholesalers: Solco Customer Service at 1-866-931-9829, Option 5 or email or fax to: customerservice@solcohealthcare.com; 1-866-931-0709, for Product Return

Press Release – Valsartan and Valsartan HCTZ Tablets Recall

FOR IMMEDIATE RELEASE - CRANBURY, NEW JERSEY, July 13, 2018 -- Prinston Pharmaceutical Inc., dba Solco Healthcare LLC., is voluntarily recalling all lots of Valsartan Tablets, 40 mg, 80mg, 160mg, and 320mg; and Valsartan-Hydrochlorothiazide Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg to the consumer level. This product recall is due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), in an active pharmaceutical ingredient by the manufacturer – Zhejiang Huahai Pharmaceutical Co. Ltd. -- in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. However, at present Prinston is unaware of any evidence that NDMA has resulted in any harm to patients taking the drugs subject to this recall. To date, Prinston Pharmaceutical Inc. has not received any reports of adverse events related to this recall.

The products are indicated for the treatment of hypertension.

Consumers and Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan should continue taking their medication, as the risk of harm to a patient’s health may be higher if the treatment is stopped immediately without any alternative treatment.

Product	NDC Code	Lot Number	Expiry Dates	Distribution Date
VALSARTAN TABLETS 40MG 30CT	43547-367-03	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN TABLETS 80MG 90CT	43547-368-09	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN TABLETS 160MG 90CT	43547-369-09	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN TABLETS 320MG 90CT	43547-370-09	All lots	From Jul 18 to Jan 20	Oct 2015 – Jun 2018
VALSARTAN/HCTZ 80MG/12.5MG 90CT TABLETS	43547-311-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 160MG/12.5MG 90CT TABLETS	43547-312-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018

VALSARTAN/HCTZ 160MG/25MG 90CT TABLETS	43547-313-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 320MG/12.5MG 90CT TABLETS	43547-314-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018
VALSARTAN/HCTZ 320MG/25MG 90CT TABLETS	43547-315-09	All lots	From Jul 18 to Jan 20	Jun 2016 – Jun 2018

The lot number and expiry date information can be found on the manufacturer's unit (see photographs below of packaged product bottle labels).

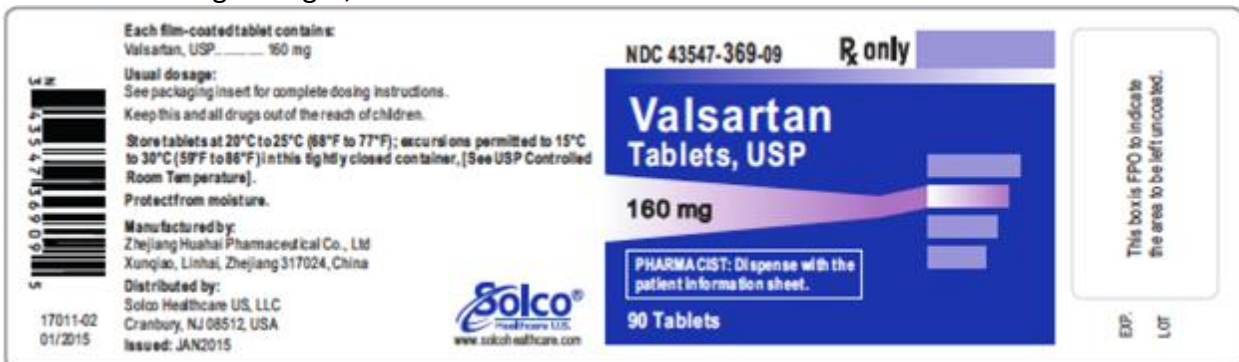
Valsartan 40 mg strength, 30 ct bottle



Valsartan 80 mg strength, 90 ct bottle



Valsartan 160 mg strength, 90 ct bottle



Valsartan 320 mg strength, 90 ct bottle

Each film-coated tablet contains:
Valsartan, USP..... 320 mg

Usual dosage:
See packaging insert for complete dosing instructions.
Keep this and all drugs out of the reach of children.

Store tablets at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) in this tightly closed container. [See USP Controlled Room Temperature].
Protect from moisture.

Manufactured by:
Zhejiang Huahai Pharmaceutical Co., Ltd
Xunqiao, Linhai, Zhejiang 317024, China

Distributed by:
Solco Healthcare US, LLC
Cranbury, NJ 08512, USA
Issued: JAN2015

17014-02
01/2015

NDC 43547-370-09 **Rx only**

**Valsartan
Tablets, USP**

320 mg

PHARMACIST: Dispense with the patient information sheet.

90 Tablets

This box is FPO to indicate the area to be left uncoated.

EXP.
LOT

Solco
Healthcare U.S.
www.solcohealthcare.com

Valsartan HCTZ 80 mg/12.5mg strength, 90 ct bottle

Each tablet contains:
80 mg of Valsartan USP and 12.5 mg of Hydrochlorothiazide USP

Usual dosage: See package insert.

Store at 20- 25°C (68- 77°F); excursions permitted to 15- 30°C (59- 86°F) [See USP Controlled Room Temperature].
Protect from moisture.

Dispense in tight container (USP).
Keep this and all drugs out of the reach of children.

Manufactured by:
Zhejiang Huahai Pharmaceutical Co., Ltd
Xunqiao, Linhai, Zhejiang 317024, China

Distributed by:
Solco Healthcare US, LLC
Cranbury, NJ 08512, USA
Issued: MAR2016

17249-01
03/2016

NDC 43547-311-09 **Rx only**

**Valsartan and Hydrochlorothiazide
Tablets, USP**

80/12.5 mg

90 Tablets

EXP.
LOT

Solco
Healthcare U.S.
www.solcohealthcare.com

Valsartan HCTZ 160 mg/12.5mg strength, 90 ct bottle

Each tablet contains:
160 mg of Valsartan USP and 12.5 mg of Hydrochlorothiazide USP

Usual dosage: See package insert.

Store at 20- 25°C (68- 77°F); excursions permitted to 15- 30°C (59- 86°F) [See USP Controlled Room Temperature].
Protect from moisture.

Dispense in tight container (USP).
Keep this and all drugs out of the reach of children.

Manufactured by:
Zhejiang Huahai Pharmaceutical Co., Ltd
Xunqiao, Linhai, Zhejiang 317024, China

Distributed by:
Solco Healthcare US, LLC
Cranbury, NJ 08512, USA
Issued: MAR2016

17252-01
03/2016

NDC 43547-312-09 **Rx only**

**Valsartan and Hydrochlorothiazide
Tablets, USP**

160/12.5 mg

90 Tablets

EXP.
LOT

Solco
Healthcare U.S.
www.solcohealthcare.com

Valsartan HCTZ 160 mg/25mg strength, 90 ct bottle

Each tablet contains:
160 mg of Valsartan USP and 25 mg of Hydrochlorothiazide USP
Usual dosage: See package insert.
Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature]. Protect from moisture.
Dispense in tight container (USP).
Keep this and all drugs out of the reach of children.
Manufactured by:
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Xunqiao, Linhai, Zhejiang 317024, China
Distributed by:
Solco Healthcare US, LLC
Cranbury, NJ 08512, USA
Issued: MAR2016
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NDC 43547-313-09 **Rx only**

**Valsartan and Hydrochlorothiazide
Tablets, USP**

160/25 mg

90 Tablets

EXP. LOT

Valsartan HCTZ 320 mg/12.5mg strength, 90 ct bottle

Each tablet contains:
320 mg of Valsartan USP and 12.5 mg of Hydrochlorothiazide USP
Usual dosage: See package insert.
Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature]. Protect from moisture.
Dispense in tight container (USP).
Keep this and all drugs out of the reach of children.
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NDC 43547-314-09 **Rx only**

**Valsartan and Hydrochlorothiazide
Tablets, USP**

320/12.5 mg

90 Tablets

EXP. LOT

Valsartan HCTZ 320 mg/25mg strength, 90 ct bottle

Each tablet contains:
320 mg of Valsartan USP and 25 mg of Hydrochlorothiazide USP
Usual dosage: See package insert.
Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature]. Protect from moisture.
Dispense in tight container (USP).
Keep this and all drugs out of the reach of children.
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Issued: MAR2016
www.solcohealthcare.com

NDC 43547-315-09 **Rx only**

**Valsartan and Hydrochlorothiazide
Tablets, USP**

320/25 mg

90 Tablets

EXP. LOT

Retail pharmacies in possession of any unused products: Valsartan Tablets, 40 mg, 80mg, 160mg, and 320mg; and Valsartan-HCTZ Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg, within expiry dates from Jul 2018 to Jan 2020 should immediately return the product by following the instructions below:

- **Pharmacists and wholesalers are asked to check their inventories, segregate any impacted inventory.**
- **Immediate discontinue use and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.**
- **Return products to:**

DLSS (Dohmen Life Science Services)
Attn: Returns Department
4580 S. Mendenhall, Memphis, TN 38141

Note: A call tag, a pre-printed, pre-paid return label will be provided to you for product return; return is free of charge. For call tag, please contact Solco Customer Service at 1-866-931-9829, Option 5, Monday through Friday (9am to 5pm EST). Wholesalers: No call is necessary, just send debit memo via email or fax to: customerservice@solcohealthcare.com; fax 1-866-931-0709.

Solco is notifying its distributors and customers by letter and email and is arranging for return of all recalled products. Pharmacies and wholesalers that received the impacted products will receive a letter as well as a copy of this press release with their recall notification information. Additional information regarding this recall's affected product lots and expiry dates can be found at <http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffectedLots.pdf> or to download at <http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffectedLots.xlsx>.

Consumers and patients with medical-related questions regarding this recall, please contact Solco at 888-679-5120 between the hours of 9:00 a.m. to 5:00 p.m. EST Monday through Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, 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 Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).