The FDA Announces a National Voluntary Recall of Several Medicines Containing Valsartan Due to an Impurity

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AUDIENCE: Pharmacy, Patient, Hospital

BACKGROUND

The United States (US) Food and Drug Administration (FDA) is alerting healthcare professionals and patients of a voluntary recall of several drug products containing the active ingredient valsartan. This recall is due to an impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled products. However, not all products containing valsartan are being recalled. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured. Companies with valsartan-containing recalled products include Prinston Pharmaceutical Inc/dba Solco Healthcare LLC, Teva Pharmaceuticals, and Major Pharmaceuticals.

Valsartan is used for the treatment of hypertension (high blood pressure) and for the treatment of heart failure. It is also indicated as a treatment for left ventricular failure and left ventricular dysfunction following myocardial infarction (heart attack). In combination with hydrochlorothiazide (HCTZ), it is used in the treatment of hypertension.

This Product Recall is being made with the knowledge of the US FDA.

ISSUE:

PRINSTON PHARMACEUTICAL

Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is recalling all lots of Valsartan Tablets, 40mg, 80mg, 160mg, and 320mg; and Valsartan-Hydrochlorothiazide Tablets, 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg to the retail level. This product recall is due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), made by the manufacturer – Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used 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. To date, Prinston Pharmaceutical has not received any reports of adverse events related to this recall.

TEVA PHARMACEUTICALS

Teva Pharmaceuticals USA confirmed a voluntary recall to the consumer/user level of 29 lots of single and 51 lots of combination valsartan medicines distributed under the Actavis label in the US due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceutical. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

MAJOR PHARMACEUTICALS

As a precautionary measure, the distribution firm, Major Pharmaceuticals, is issuing a nationwide voluntary recall of all lots within expiry of valsartan, which were supplied by Teva Pharmaceuticals and labeled as Major Pharmaceuticals.

ADDITIONAL INFORMATION:

PRINSTON PHARMACEUTICAL

Retail pharmacies in possession of any unused products: Valsartan Tablets, 40mg, 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:

- Please contact Solco Customer Service at 1-866-931-9829, Option 5, Monday through Friday (9am to 5pm EST) or email or fax to: customerservice@solcohealthcare.com; 1- 866-931-0709, for the Product Return.
- A call tag, a pre-printed, pre-paid return label will be provided to you for product return; return is free of charge.
- Return products to:
  DLSS (Dohmen Life Science Services) Attn: Returns Department
  4580 S. Mendenhall, Memphis, TN 38141

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.

If you have any questions regarding this recall, please call 1-866-931-9829, Option 5, 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. Additional information regarding this recall affected products' lots and expiry dates can be found at:
http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffactedLots.pdf

or to download at
http://www.solcohealthcare.com/uploads/news/ValsartanHCTZRecallAffactedLots.xlsx.

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.

TEVA PHARMACEUTICALS

Teva is notifying its Direct Accounts by FedEx Overnight mailing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts of this product recall and making arrangements for impacted product to be returned to Inmar. Instructions for returning recalled products and crediting are given in the recall letter.

Customers and patients with Medical-related Questions, information about an Adverse Event or other questions about the Teva product's being recalled should contact Teva's Medical Information by phone at: 888-838-2872, option 3.

- 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.

Adverse reactions or quality problems experienced with the use of this product may 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.
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm.

MAJOR PHARMACEUTICALS

Consumers with questions regarding this recall should contact Major Pharmaceuticals Customer Support at 1-800-616-2471, Option #1 available Monday through Friday 8 a.m. – 8 p.m. EST. Consumers can contact their physician or healthcare provider if they have additional questions about this product.

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.

PRODUCT DESCRIPTION:

LINKS:
For additional details regarding this recall, please visit the links provided.

- FDA Press Announcement: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm.
- Prinston Recall Notice: https://www.fda.gov/Safety/Recalls/ucm613504.htm.
- Teva Recall Notice: https://www.fda.gov/Safety/Recalls/ucm613729.htm.
- Major Recall Notice: https://www.fda.gov/Safety/Recalls/ucm613625.htm.