ProCare Rx

URGENT NOTICE

TYPE: Drug Recall

Valsartan-Containing Products: Update Health Professional and Consumer on Recent Recalled Products

Drug Name: **Valsartan**

Audience: Consumer, Health Professional, Pharmacy

Date: **07/19/2018**

ISSUE

The investigation into valsartan-containing products is ongoing and the following list may change. We will update this statement as we have more information.

There are currently three voluntary recalls related to the NDMA impurity detected in the valsartan API:

- **Teva Pharmaceuticals USA labeled as Major Pharmaceuticals** — recall is at the retail level because these products are only used in facilities where they are directly administered to patients by health care professionals: Valsartan 80mg and 160mg products.
- **Prinston Pharmaceuticals Inc. labeled as Solco Healthcare LLC** — recall is at the consumer/user level: Valsartan 40mg, 80mg, 160mg, and 320mg; and valsartan/HCTZ 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg products.
- **Teva Pharmaceuticals labeled as Actavis LLC** — recall is at the consumer/user level: Valsartan 40mg, 80mg, 160mg, and 320mg; and valsartan/HCTZ 80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg, and 320mg/25mg products.

BACKGROUND

Valsartan is used to treat high blood pressure and heart failure. Not all products containing valsartan are being recalled. This update will clarify which valsartan-containing products are being recalled.

The recalled products contain an impurity, N-nitrosodimethylamine (NDMA), in the API manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China. The presence of the potentially cancer-causing NDMA was unexpected, and the agency believes the NDMA is related to changes in the way the active substance was manufactured. Some levels of the impurity may have been in the valsartan-containing products for as long as four years.

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RECOMMENDATION

Patients should be aware that not all valsartan-containing medications are affected and being recalled and if you have questions, you should ask your pharmacist or health care provider. Patients should:

- Compare the information on your prescription bottle with the information in this list (company, National Drug Code, lot number) to determine if your current medicine has been recalled.
- Continue taking your current medicine until your health care provider or pharmacist gives you a replacement or a different treatment option.

Health professionals should know:

- The FDA has determined the recalled valsartan products pose an unnecessary risk to patients. Therefore, the FDA recommends patients use valsartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition.
- If you have medication samples from these companies, quarantine the products and do not provide them to patients.