IMPORTANT **RECALL NOTICE**

JULY 2018

Valsartan-Containing Products Recalled By Some Manufacturers

On July 13th, the FDA announced a recall of medications containing Valsartan, a generic medication used to treat high blood pressure and heart failure from multiple manufacturers due to an impurity detected in the recalled products. The Food and Drug Administration has stated that because Valsartan is used to treat serious medical conditions, patients taking a recalled Valsartan-containing medication should continue taking their medicine until they have an alternative therapy or new supply.

Which Valsartan Containing Products Are Affected By The Recall?

- Valsartan with Hydrochlorothiazide manufactured by Alembic is NOT affected by this recall.
- You can find additional information regarding this recall on the FDA website:

  https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm

  - Solco Healthcare recall information - https://www.fda.gov/Safety/Recalls/ucm613504.htm
  - Major Pharmaceuticals recall information - https://www.fda.gov/Safety/Recalls/ucm613625.htm
  - Teva Pharmaceuticals recall information - https://www.fda.gov/Safety/Recalls/ucm613729.htm

What Do I Need To Know?

- Because multiple manufacturers are impacted by this recall, there is limited supply of Valsartan containing products in the market place, specifically single ingredient Valsartan drug products. It is very important that you speak with your prescriber about an alternative therapy and send in a new prescription for that new drug therapy. Refilling your existing prescription may result in a delay in processing and receipt of a different medication than originally prescribed.
- The Food and Drug Administration has stated that patients who have the recalled medicine should continue taking it until they have a new supply unless otherwise directed by their healthcare provider. You should NOT discontinue taking your medication without direct guidance from your doctor.

Why Was This Medication Recalled?

- This voluntary recall is being issued by the manufacturers working with the FDA because an impurity, N-nitrosodimethylamine (NDMA), was detected in the recalled products. However, not all products containing Valsartan are being recalled.
- Any suspected adverse events that may be related to the use of these products should be reported to your doctor. You can also report adverse events that may be related to this recall to FDA's Med Watch Program either online, by regular mail or by fax.

  - Online: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
  - Regular Mail: Use postage-paid, pre-addressed Form FDA 3500B available at: http://www.fda.gov/MedWatch/getforms.htm. Mail to the address on the pre-addressed form. **Fax: 1-800-332-0178** (toll free)