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Major Pharmaceuticals Issues Voluntary Nationwide Recall of Valsartan Due to the Potential Presence of a Probable Carcinogen (NDMA)

LIVONIA, MI July 13, 2018 — 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.

Major Pharmaceuticals is committed to patient safety and is partnering with the Food and Drug Administration (FDA) to notify customers who may be in possession of Valsartan tablets supplied by Teva Pharmaceuticals. Please see the below list of affected products and lot numbers.

The products subject to this recall were distributed nationwide to **wholesale and retail facilities, including hospitals and pharmacies**. Through recent communication with FDA, Major Pharmaceuticals learned of a potential issue with the active pharmaceutical ingredient in Valsartan supplied by Teva Pharmaceuticals which may contain the probable carcinogen N-nitrosodimethylamine (NDMA). Major Pharmaceuticals as a distribution firm, is recalling all lots within expiry of Valsartan supplied by Teva Pharmaceuticals. Major Pharmaceuticals has not received any reports of adverse events related to this recall to date.

Valsartan is a prescription medication that is commonly used to treat high blood pressure and heart failure. The product was distributed as unit dose blisters with 100 tablets per carton. The distribution firm is notifying distributors and other customers by recall letter and arranging for return of all recalled products. Consumers should contact their doctor for further guidance and potential change of treatment before they stop taking this product. Pharmacies, and healthcare facilities that have product being recalled should stop using and dispensing the product immediately.

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

This recall is being conducted with the full knowledge of the U.S. FDA.

MAJOR PHARMACEUTICALS

Product Description	NDC Number	Item Number	Lot Number	Expiration Date
Valsartan 80mg Tablets, USP	0904-6594-61	302086	T01795	05/2019
			T01807	05/2019
			T01712	02/2019
			T01625	02/2019
			T01596	02/2019
			T01500	02/2019
			T01466	07/2018
Valsartan 160mg Tablets, USP	00904-6595-61	302087	T01646	05/2019
			T01788	05/2019
			T01668	05/2019
			T01524	02/2019
			T01269	07/2018



About Major Pharmaceuticals

For more than 30 years, Major® has been offering a broad and expanding portfolio of Rx unit dose, bulk and OTC options focused on supporting patient care efforts and providing economic value.