URGENT NOTICE

TYPE: Drug Recall

Product impurity detected above specification limits

Drug Name: **Amlodipine/Valsartan Combination Tablets and Amlodipine/Valsartan/Hydrochlorothiazide Combination Tablets**

Audience: Patient

Date: **11/27/2018**

ISSUE

Teva Pharmaceuticals has initiated a voluntary recall in the United States, to the patient level, of all lots of Amlodipine / Valsartan combination tablets and Amlodipine / Valsartan / Hydrochlorothiazide combination tablets due to an impurity detected above specification limits in an active pharmaceutical ingredient (API) manufactured by Mylan India. The impurity found in Mylan's valsartan API is known as N-nitroso-diethylamine (NDEA), which has been classified as a probable human carcinogen. This chemical is typically found in very small amounts in certain foods, drinking water, air pollution, and certain industrial processes.

Amlodipine/Valsartan combination tablets and Amlodipine/Valsartan/Hydrochlorothiazide combination tablets are used for the treatment of high blood pressure. To date, Teva has not received any reports of adverse events signaling a potential link or exposure to valsartan.

Patients taking Amlodipine / Valsartan combination tablets or Amlodipine / Valsartan / Hydrochlorothiazide combination tablets are advised to continue taking their medication and to contact their pharmacist or physician for advice on alternative treatment. The risk of harm to a patient's health may be higher if the treatment is stopped immediately without any comparable alternative treatment.

RECOMMENDATION

Customers and patients with medical-related questions, information about an Adverse Event or other questions about the Teva products being recalled should contact Teva's Medical Information by phone at: 888-838-2872, option 3, then, option 4. 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 other problems experienced with the use of the products may also 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.