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Mylan recalls batches of blood-pressure drug containing valsartan

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Valsartan is used to treat high blood pressure for treating heart failure. It's also used in combination with amlodipine or hydrochlorothiazide to treat high blood pressure.



Singapore - Mylan N.V. announced that its U.S. based Mylan Pharmaceuticals business is conducting a voluntary nationwide recall to the consumer level of select lots of Valsartan-containing products, including six lots of Amlodipine and Valsartan Tablets, USP (including the 5mg/160mg, 10mg/160mg, and 10mg/320mg strengths), seven lots of Valsartan Tablets, USP (including 40 mg, 80 mg, 160 mg, and 320 mg strengths), and two lots of Valsartan and Hydrochlorothiazide Tablets, USP 320mg/25mg strength. These products are being recalled due to detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA 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 according to the International Agency for Research on Cancer (IARC).

Valsartan is used to treat high blood pressure for treating heart failure. It's also used in combination with amlodipine or hydrochlorothiazide to treat high blood pressure.

Patients on valsartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.