

Novartis Pharmaceuticals Corporation (Novartis) Statement on Recall Outside the United States of Sandoz Generic Valsartan and Sandoz Valsartan and Hydrochlorothiazide Film-Coated Tablets

Jul 16, 2018

Specific batches of Sandoz valsartan and Sandoz Valsartan and Hydrochlorothiazide Film-Coated Tablets were recalled **outside of the United States** earlier this month.

This recall does NOT impact any Novartis or Sandoz valsartan products in the United States or any Novartis Pharma products that contain valsartan, including Diovan® (valsartan), Diovan HCT® (valsartan/hydrochlorothiazide), Exforge® (amlodipine and valsartan), Exforge HCT® (amlodipine, valsartan and hydrochlorothiazide) or Entresto® (sacubitril/valsartan). Also, Sandoz valsartan products outside the specifically defined markets below are not impacted by the issue.

The valsartan API (active pharmaceutical ingredient) in these products does not come from the same source as those products affected outside the United States. Patients in the United States currently taking Sandoz valsartan tablets, Sandoz valsartan and hydrochlorothiazide tablets, Sandoz amlodipine and valsartan tablets, Sandoz amlodipine, valsartan, hydrochlorothiazide tablets, Diovan®, Diovan HCT®, Exforge®, Exforge HCT® or Entresto® should continue to take their medication as directed by a physician.

The recall was initiated in the following countries after an impurity above the typically established limit was confirmed: Germany, Norway, Finland, Sweden, Hungary, Netherlands, Austria, Ireland, Bulgaria, Italy, Spain, Portugal, Belgium, Luxembourg, France, Poland, Croatia, Lithuania, Greece, Canada, Bosnia and Herzegovina, Bahrain and Malta.

The health authorities in the concerned countries were notified about the issue as per local regulations on June 27, 2018. Novartis is in close contact with the health authorities and the supplier.

On July 13, 2018, the United States Food and Drug Administration announced a separate recall of valsartan from non-Sandoz companies. **This recall does NOT impact any Novartis or Sandoz valsartan products in the United States.**

Novartis and Sandoz are committed to meeting the highest quality standards for all of our marketed products, and the recall outside the United States is being conducted in agreement with the local health authorities impacted.

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