

## Immediate Release:

# Expansion of Irbesartan Recall

On January 18, 2019, Prinston Pharmaceutical Inc., doing business as Solco Healthcare LLC., announced the voluntary recall of one lot of irbesartan 300 mg tablets and seven lots of irbesartan/hydrochlorothiazide (HCTZ) combination tablets. The products are being recalled due to the presence of the NDEA (N-nitrosodiethylamine) impurity.

The U.S. Food and Drug Administration (FDA) previously released interim acceptable daily intake thresholds for impurities found in this class of medications known as angiotensin II receptor blockers or ARBs. Prinston is recalling the specific lots due to NDEA levels above the interim acceptable thresholds. Irbesartan and irbesartan/HCTZ are used for treating high blood pressure and heart failure.

Patients with impacted product are instructed to continue taking the medication until a replacement product or alternative therapy is available. The risk of harm may be greater if the ARB therapy is discontinued abruptly without an alternative agent being initiated. For a complete listing of affected products' NDCs, lot numbers and expiration dates, view the [company announcement](#).

This class of medications has experienced ongoing recalls since July 2018. For additional details, view the FDA's [update page](#). For a complete listing of irbesartan products that have been recalled, visit the FDA [website](#). CastiaRx plans to provide ongoing communication regarding the FDA's investigation of the impurities recently found in this class of medications.

### References:

1. Prinston Pharmaceutical Inc. issues voluntary nationwide recall of irbesartan and irbesartan HCTZ tablets due to detection of a trace amount of unexpected impurity, N- nitrosodiethylamine (NDEA) in the products. Company Announcement. <https://www.fda.gov/Safety/Recalls/ucm629627.htm>. Updated January 18, 2019. Accessed January 18, 2019.
2. FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan. FDA Drug Safety and Availability. <https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm>. Updated January 18, 2019. Accessed January 18, 2019.