

Alerts and Recalls

Generic Name (Trade Name—Company)

November 1, 2018

Irbesartan

(No trade names—Aurobindo)

Aurobindo recalls 22 batches of drug substance because of NDEA impurity

Uses/Notes

[Aurobindo Pharma is voluntarily recalling](#) 22 batches of irbesartan drug substance because they contain *N*-nitrosodiethylamine (NDEA). NDEA, which occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen by the International Agency for Research on Cancer.

These 22 batches of irbesartan drug substance were supplied to ScieGen Pharmaceuticals to manufacture the finished irbesartan drug product.

Aurobindo has notified ScieGen of the recall and is arranging for the return of all available irbesartan drug substance. Aurobindo Pharma Limited has further advised ScieGen to contact its distributors and retailers to return irbesartan drug product and finished irbesartan tablets that have been identified by Aurobindo.

Patients should contact their pharmacist or physician for advise on an alternative treatment before returning their medication. Patients who are on irbesartan should continue taking their medication, as the risk of harm to a patient's health may be higher if treatment is stopped immediately without an alternative treatment.

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