

## 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.

### Source URL:

<http://aphanet.org/alerts-and-recalls/aurobindo-recalls-22-batches-drug-substance-because-ndea-impurity>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.