Generic Name:
Irbesartan
Trade Name:
No trade names
Company:
ScieGen
Notes:

FDA is alerting patients and health professionals to ScieGen?s voluntary recall of certain lots of irbesartan, an angiotensin II receptor blocker (ARB), because they contain *N*-nitrosodiethylamine (NDEA), a known animal and suspected human carcinogen.

FDA laboratory testing confirmed NDEA in some lots of ScieGen?s irbesartan. ScieGen?s irbesartan products are labeled as Westminster Pharmaceuticals and Golden State Medical Supply (GSMS). See the list of irbesartan products under recall.

This is the first nonvalsartan drug product the agency has found to contain the NDEA impurity.

In addition, Aurobindo, which manufactures the active pharmaceutical ingredient (API) for ScieGen?s irbesartan products, is recalling all unexpired lots of its irbesartan API supplied to the U.S. market with NDEA. FDA and Aurobindo laboratory testing confirmed NDEA in certain lots of the Aurobindo's irbesartan API.

FDA reminds patients taking any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. Not all ARBs contain NDEA or *N*-nitrosodimethylamine (NDMA), so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

To date, ScieGen is the only manufacturer of irbesartan drug products found to contain NDEA.

FDA continues to test all ARBs for the presence of impurities and has publicly posted two methods for manufacturers and regulatory agencies around the world to test their ARBs for the unexpected NDMA and NDEA impurities. The combined headspace method and the combined direct injection method can detect and quantify NDMA and NDEA simultaneously in ARB API and finished drug products.

FDA continues to work with API and drug manufacturers to ensure their products are not at risk for NDMA or NDEA formation.

Medication Monitor Categories:
Alerts and Recalls