ScieGen Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg due to the Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient (API)

Please find FAQ on this topic , if you have specific questions you may call Toll free Number: (1)-855-724-3436

If you are taking Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg were manufactured by ScieGen Pharmaceuticals Inc and are labeled as Westminster Pharmaceuticals and Golden State Medical Supply, Inc [GSMS], please check the lot number whether it is affected or not and call specific numbers as provided in the recall notice.

Q : Why this recall is triggered ?

A : ScieGen Pharmaceuticals, Inc. is voluntarily recalling listed lots, within expiry, of Irbesartan Tablets, USP 75 mg, 150 mg, and 300 mg dosage forms to the consumer level. "These products are being recalled due to the presence of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Irbesartan, USP manufactured by Aurobindo Pharma Limited".

Q: What is the origin of the impurity N-nitrosodiethylamine (NDEA)
A: This impurity is found in the few API lots manufactured by Aurobindo pharma Limited . Aurobindo has announced a recall of 22 lots of API .

Q : All the lots of Sciegen Manufactured Irbesartan Lots are affected by this recall ?
A : Not all the lots of Irbesartan manufactured by Sciegen are affected, the lots containing the NDEA impurity are listed on the recall.

Q: How do I know which are the affected lots
A : Please refer to the recall notice for the complete list of affected lots.

Q: **Are all the products manufactured by Sciegen are affected by N-Nitrosodiethylamine (NDEA) ?**
A : No, Irbesartan is the only product affected as manufactured by Sciegen affected by this recall.

Q : What are the levels of NDEA found in Irbesartan Tablets ?
A : Sciegen has analyzed NDEA content in all the drug product lots and found varying contents from 0.03 to 0.44 ppm.

Q : What is the allowed limit ?
A : As of now the limit is under evaluation by USFDA, these batches are recalled on precautionary basis.

Q: If you are the consumer or caretaker what next?

- ✓ Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to 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 the treatment is stopped immediately without any alternative treatment.
- ✓ Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using Irbesartan.

Q: If any other questions or Adverse Events?

- ❖ If the product labeled/distributed by Golden State Medical Supply Incorporated [GSMS]: Call (800) 284-8633 Ext: 215
- ❖ If the product labeled/distributed by Westminster Pharmaceuticals, LLC: Call 888-354-9939
- ❖ If the labeler/distributor information not available: Call ScieGen Pharmaceuticals Inc at 855-724-3436

Q: Tablets available on your shelf? Return Products?

If the product labeled/distributed by Westminster Pharmaceuticals, LLC:

Patients should return the affected medication to their pharmacy. Pharmacies should return their affected stock to their wholesaler.

If you have further questions regarding the recall, please email recalls@wprx.com or contact Jonathan Olive, Director of Regulatory Affairs, M-F 9:00AM – 5:00PM EST at 813-607-6672

If the product labeled/distributed by Golden State Medical Supply Incorporated [GSMS]:

Contact Golden State Medical Supply Incorporated for directions on return authorizations by calling (800) 284-8633 Ext. 215 between 7:30 a.m.-4 p.m. Pacific or email **recalls@gsms.us.**