ScieGen Pharmaceuticals – Recall of Irbesartan Update

- On October 30, 2018, ScieGen Pharmaceuticals announced an update to the consumer-level recall of several lots of irbesartan tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient (API) manufactured by Aurobindo Pharmaceuticals.
    - Irbesartan tablets were manufactured by ScieGen Pharmaceuticals and labeled as Westminster Pharmaceuticals and Golden State Medical Supply.
    - The recall by Westminster Pharmaceuticals announced on October 29, 2018, has been updated to include additional lots of irbesartan marketed by Golden State Medical Supply.
- NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer classification.
- To date, ScieGen Pharmaceuticals has not received any reports of adverse events related to this recall.
- To date, only the following lots are being recalled:

Labeler	Product Description	NDC#	Lot# (Expiration Date)
Westminster Pharmaceuticals	irbesartan 75 mg tablets, 30 count bottle	69367-119-01	B160002A (9/2019)
	irbesartan 75 mg tablets, 90 count bottle	69367-119-03	B160002B (9/2019)
	irbesartan 150 mg tablets, 30 count bottle	69367-120-01	C161002A (2/2020); B161005A (9/2019)
	irbesartan 150 mg tablets, 90 count bottle	69367-120-03	C161002B (2/2020); B161005B (9/2019)
	irbesartan 300 mg tablets, 30 count bottle	69367-121-01	C162002A (2/2020); B162008A (9/2019)
	irbesartan 300 mg tablets, 90 count bottle	69367-121-03	C162002B (2/2020); B162008B (9/2019)
Golden State Medical Supply	irbesartan 75 mg tablets, 90 count bottle	60429-640-90	B160003 (9/2019); B160004 (9/2019)
	irbesartan 150 mg tablets, 30 count bottle	60429-641-30	GS019526 (11/2019); GS020252 (11/2019); GS020958 (11/2019)
	irbesartan 150 mg tablets, 90 count bottle	60429-641-90	B161003 (9/2019); B161004 (9/2019); B161006 (9/2019); B161007 (9/2019); B161008 (11/2019); B161009 (11/2019);

Continued . . .

			B161010 (11/2019); C161001 (2/2020); C161003 (5/2020)
	irbesartan 300 mg tablets, 30 count bottle	60429-642-30	GS019036 (9/2019); GS019073 (9/2019); GS021472 (11/2019); GS021530 (11/2019); GS022234 (2/2020)
	irbesartan 300 mg tablets, 90 count bottle	60429-642-90	B162009 (9/2019); B162010 (9/2019); B162011 (9/2019); B162012 (11/2019); B162013 (11/2019); B162014 (11/2019); B162015 (11/2019); C162001 (2/2020)

- Irbesartan is used to treat hypertension (HTN) and for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (> 300 mg/day) in patients with type 2 diabetes and HTN.
- Patients with recalled product are advised to return the recalled medication to their pharmacy. Pharmacies should return their recalled stock to their wholesaler.
    - Patients can check if they have the recalled irbesartan by examining their tablets. The recalled tablets are white, oval shaped, and marked with SG 160; SG 161; or SG 162.
- 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 healthcare provider if they have experienced any problems that may be related to using the recalled irbesartan.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- For more information regarding this recall, contact Westminster Pharmaceuticals by phone at **1-888-354-9939** or email at **recalls@wprx.com**, or contact Golden State Medical Supply by phone at **1-800-284-8633** or email at **recalls@gsms.us**.