2002 Eastpark Blvd. Ste. A
Cranbury, NJ 08512
Tel: (609) 451-1000 I Fax: (609) 451-1100

www.solcohealthcare.com

URGENT DRUG RECALL

CUSTOMER NOTIFICATION / RECALL COMMUNICATION

Irbesartan Tablets 300mg 90 ct. and
Irbesartan HCTZ 150/12.5mg & 300/12.5mg Tablets 30 and 90 ct.

Date: January 18, 2019

Dear Valued Customer:

This letter is to inform you that Solco Healthcare is voluntarily recalling the following product(s):

Product	NDC Code	Lot Number	Expiry Dates	Distribution Date
IRBESARTAN TABLETS 300MG 90CT	43547-376-09	331B18009	02/2021	8/9/2018
IRBESARTAN/HCTZ 300MG/12.5MG 30CT TABLETS	43547-331-03	327A18001	03/2021	7/10/2018
IRBESARTAN/HCTZ 300MG/12.5MG 30 CT TABLETS	43547-331-03	327A18002	03/2021	7/10/2018
IRBESARTAN/HCTZ 300MG/12.5MG 90CT TABLETS	43547-331-09	327B18008	03/2021	7/10/2018
IRBESARTAN/HCTZ 300MG/12.5MG 90CT TABLETS	43547-331-09	327B18009	03/2021	7/10/2018
IRBESARTAN/HCTZ 150MG/12.5MG 30CT	43547-330-03	325D18004	03/2021	7/10/2018
IRBESARTAN/HCTZ 150MG/12.5MG 90CT TABLETS	43547-330-09	325B18004	03/2021	8/24/2018
IRBESARTAN/HCTZ 150MG/12.5MG 30CT TABLETS	43547-330-03	325D18005	03/2021	7/10/2018

This recall has been initiated due to detecting NDEA impurity above the advisable limit (0.088ppm). To date, Solco Healthcare has not received any reports of adverse events related to this recall.

This recall is being made with the knowledge of the Food and Drug Administration and should be carried out to the consumer level.

The products are indicated for the treatment of hypertension. Prinston Pharmaceutical Inc. dba Solco Healthcare LLC. is voluntarily recalling specific lots of Irbesartan Tablets, 300mg/90 ct. and Irbesartan HCTZ, 150/12.5mg and 300/12.5mg/30 and 90 ct. to consumer level. This product recall is due to the detection of a trace amount of an unexpected impurity, NDEA, made by the manufacturer- Zhejiang Huahai Pharmaceutical Co. Ltd. -- that is used in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

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Retail pharmacies in possession of any unused products: Irbesartan 300mg/90 ct. and Irbesartan HCTZ 150/12.5mg, 300/12.5mg in 30 and 90 ct. with the above lots and expiry dates should immediately return the product by following the instructions below:

- Immediately examine your inventory and quarantine product subject to recall.
- Immediately discontinue use and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.

Return product to:

Eversana
ATTN: Returns Department C/O Solco Healthcare
4580 S. Mendenhall Rd.
Memphis, TN 38141

NOTE: A return label will be provided to you, free of charge. For the call tag, contact customer service via email customerservice@solcohealthcare.com, fax 1-866-931-0709 or contact Customer Service at 1-866-931-9829 option #5.

Wholesalers: No call necessary, just send debit memo via email: customerservice@solcohealthcare.com or fax 1-866-931-0709.

Please complete and return the enclosed "Customer Recall Response Form" as soon as possible and fax the form to us at 1-901-368-6903. The completed form may also be emailed to: DDNRegulatory@ddnnet.com. Solco is notifying its distributors and customers by letter and email and is arranging for return of all recalled products.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product. Reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call1-800-332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178.

We apologize for any inconvenience this may cause you. If you have any questions, please do not hesitate to call:

Wholesalers/Distributors/Retail Pharmacies contact: Solco Customer Service at 1-866-931-9829, option 5; M-F 8 a.m. - 7 p.m. CST.
All others contact Stericycle Customer Service at: 1-888-871-7116

Sincerely,

Remonda Gergis
VP, Quality and Compliance

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Solco Healthcare U.S.

RECALL RESPONSE FORM

Product	NDC Code	Lot Number	Quantity of Bottles Returned	Expiry Dates	Distribution Date	Unit of Measure (each)
IRBESARTAN 300MG 90CT TABLETS	43547-376-09	331B18009		02/2021	8/9/2018	
IRBESARTAN/HCTZ 300MG/12.5MG 30CT TABLETS	43547-331-03	327A18001		03/2021	7/10/2018	
IRBESARTAN/HCTZ 300MG/12.5MG 30 CT TABLETS	43547-331-03	327A18002		03/2021	7/10/2018	
IRBESARTAN/HCTZ 300MG/12.5MG 90CT TABLETS	43547-331-09	327B18008		03/2021	7/10/2018	
IRBESARTAN/HCTZ 300MG/12.5MG 90CT TABLETS	43547-331-09	327B18009		03/2021	7/10/2018	
IRBESARTAN/HCTZ 150MG/12.5MG 30CT	43547-330-03	325D18004		03/2021	7/10/2018	
IRBESARTAN/HCTZ 150MG/12.5MG 90CT TABLETS	43547-330-09	325B18004		03/2021	8/24/2018	
IRBESARTAN/HCTZ 150MG/12.5MG 30CT TABLETS	43547-330-03	325D18005		03/2021	7/10/2018	

Please complete. Check ALL applicable.

☐ I have read and understand the recall instructions provided in the recall letter and that this recall is being carried out to the consumer level.

☐ I have checked my inventory and have quarantined the product consisting of _____ units.
Indicate disposition of this recalled product:

- ☐ Returned (quantity: _____; date: _____; method :_____)
- ☐ Held in Quarantine for return
- ☐ Other:_____

☐ I have contacted customer service (below) for a pre-paid return label.
Total of Call Tags (Number of Boxes you will be returning): _____

Return product to:

Eversana
ATTN: Returns Department C/O Solco Healthcare
4580 S. Mendenhall Rd.
Memphis, TN 38141

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Wholesalers: No call necessary, just send debit memo via email or fax to: customerservice@solcohealthcare.com or fax 1-866-931-0709.

☐ I have or will contact those further distributed to, this recall is to the consumer level.

Any adverse events associated with this recalled product? ☐ Yes ☐ No
If yes, please explain:_____

Check the appropriate box(es) to describe your business:

☐ Wholesaler/distributor ☐ Hospital/medical facility
☐ Pharmacy-retail ☐ Other:_____

Contact Information:

Name:_____

Title:_____

Tel Number:_____

Email:_____

Facility:_____

Address:_____

City, State Zip:_____

Facility DEA:_____

Wholesaler:_____

Wholesaler Account#:_____

Date:_____

PLEASE SEND THIS COMPLETED RECALL RESPONE FORM TO THE FAX OR EMAIL BELOW:
FAX: 1-901-368-6903
EMAIL TO: DDNRegulatory@ddnnet.com