RXADVANCE
136 Turnpike Rd
Southborough, MA 01772

metformin hydrochloride ER tablets Recall Alert

Date of Notice: 01/12/2022

Brief Description of Recall Alert

Viona Pharmaceuticals Inc. is voluntarily recalling thirty-three (33) lots of metformin hydrochloride extended-release (ER) tablets, USP 750 mg. Lot number M008132 was found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. As a precautionary measure, a voluntarily recall of all the marketed 33 batches. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India for U.S. distribution by Viona Pharmaceuticals Inc.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin HCl ER tablets, USP 750 mg	72578-036-01	M008130 M008131 M008132 M008133	06/2022
metformin HCl ER tablets, USP 750 mg	72578-036-01	M010080 M010081	07/2022
metformin HCl ER tablets, USP 750 mg	72578-036-01	M011029 M011030 M011031 M011032 M011034	08/2022
metformin HCl ER tablets, USP 750 mg	72578-036-01	M013394 M013395 M013966 M013967	09/2022
metformin HCl ER tablets, USP 750 mg	72578-036-01	M100831 M100832	12/2022
metformin HCl ER tablets, USP 750 mg	72578-036-01	M100833 M100834 M101267 M102718 M102719 M102720	01/2023
metformin HCl ER tablets, USP 750 mg	72578-036-01	M102721	02/2023

		M102722 M104172 M104173 M104174 M104175 M104176	
metformin HCl ER tablets, USP 750 mg	72578-036-01	M105889 M105890	03/2023

Prescriber Information

Viona Pharmaceuticals Inc., is notifying its customers by email and mail (FedEx Overnight) and is arranging for return of all recalled products to the recall processor at the following address:

Eversana Life Science Services
c/o Viona recall
ATTN: Returns Department
4580 S. Mendenhall Rd.
Memphis, TN 38141

For questions regarding this recall, contact the recall processor by phone at 1-888-304-5022, option 1; Monday – Friday, 8:00 am – 7:00 pm CDT.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 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

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the products being recalled, should contact Viona Pharmaceuticals Inc., by phone at 1-888-304-5011, Monday - Friday, 8:30 am – 5:30 pm, EST.

RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.