RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Metformin Recall Alert

Date of Notice: 06/11/2021

Brief Description of Recall Alert

Viona Pharmaceuticals Inc., is voluntarily recalling 2 (two) lots of metformin hydrochloride extended-release tablets, USP 750 mg to the retail level. The 2 (two) lots of metformin hydrochloride extended-release tablets, USP 750 mg have been found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India in November 2019, for U.S. distribution by Viona Pharmaceuticals Inc.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin hydrochloride extended-release tablets USP 750 mg	72578-036-01	M915601 M915602	10/2021

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 our recall processor at the following address

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

Consumers with questions regarding this recall can contact FDA's recall processor Eversana Life Science Services by phone at 1-888-304-5022, option 1; Monday – Friday, 8:00 am – 7:00 pm CDT. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

Customers 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: 888-304-5011, Monday - Friday, 8:30 am – 5:30 pm, EST.

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RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option.