June 14, 2021 **COM-2021-033**

RECALL NOTIFICATION

FDA PUBLICATION DATE: June 11, 2021

DRUG NAME: Metformin Hydrochloride Extended-Release Tablets

COMPANY: Viona Pharmaceuticals Inc.

REASON: Contains Nitrosodimethylamine (NDMA) impurities

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. Therefore, the clinical team wants to communicate the latest up-to-date information on drug recalls. For this reason, we are notifying you that on June 11, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary drug recall for two lots of the following product: Metformin HCl Extended-Release Tablets, USP 750 mg, manufactured by Cadila Healthcare Limited, Ahmedabad, India and distributed by Viona Pharmaceuticals Inc.

The voluntary recall is due to quality test results showing that drug lots contain Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. NMDA is a potential carcinogen. No adverse events have been reported related to the recalled drug.

Affected product:

NDC	Product description	Batch No.	Expiration Date
72578-0036-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg	M915601	Oct-2021
		M915601	Oct-2021

Pharmacy required action(s):

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider.

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- Patients experiencing any problem while taking or using this product must contact their physician.

Contact information:

- Viona Pharmaceuticals Inc. is making arrangements with customers for returning the recalled drug to the following address:

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

- For questions:
  - Consumers should contact Eversana Life Science Services by phone at 1-888-304-5022, option 1; Monday – Friday, 8:00 am – 7:00 pm CDT
  - Customers should contact Viona Pharmaceuticals Inc. by phone at: 888-304-5011, Monday - Friday, 8:30 am – 5:30 pm, EST for medical-related questions.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program in any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, please call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2021). Viona Pharmaceuticals Inc., Issues Voluntary Nationwide Recall of Metformin HCl Extended-Release Tablets, USP 750 mg, Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity. Retrieved June 14, 2021, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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