COMMUNICATION

2022-002

05 JANUARY 2022

URGENT PLEASE REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

12/28/2021

Drug Information:

National Drug Code

72578-036-01

Product Description

Metformin hydrochloride extended-release (ER) 750mg tablet

Batch Number

Refer to FDA website for a complete list

Expiration Date

Refer to FDA website for a complete list

Company:

Viona Pharmaceuticals, Inc.

QUESTIONS

Call Eversana Life Science Services at 1-888-304-5022 (option 1) Monday – Friday from 8:00 a.m. to 7:00 p.m. CST.

Metformin Hydrochloride ER

It is for this reason that we are notifying you that on 12/28/2021 the US Food and Drug Administration published a drug recall for the following product: Metformin HCl ER 750mg tablets

Pharmacy Required Action:

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

Reason for Recall:

Viona Pharmaceuticals Inc., is voluntarily recalling 33 lots of metformin hydrochloride extended-release tablets, USP 750mg to the retail level. The reason for the recall is due to the detection of N-nitrosodimethylamine (NMDA) in the long-term stability samples. This product was manufactured by Cadila Healthcare Limited for U.S. distribution by Viona Pharmaceuticals Inc.

NMDA is classified as a probable human carcinogen. It is a known environmental contaminant and found in water and foods. To date, neither Viona Pharmaceuticals Inc., nor Cadila Healthcare Limited have received any reports of adverse events related to this recall.

Viona Pharmaceuticals Inc. is notifying its customers by email and mail and is arranging for return of all recalled products at the following address:

Eversana Life Science Services

c/o Viona Recall

ATTN: Returns Department

4580 S. Mendenhall Rd.

Memphis, TN 38141

CLINICAL PEARLS BY PHARMPIX

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 by 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, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

pharmpix
POWERED BY ONEARK

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:
1. U.S. Food and Drug Administration. (2021). Viona Pharmaceuticals Inc., Issues Voluntary Nationwide Recall of Metformin HCl Extended-Release Tablets, USP 750mg, Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
FRM-CL-000126-000

CLINICAL PEARLS BY PHARMPIX