COMMUNICATION

COM-2023-079

12
DECEMBER
2023

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 the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

12/11/2023

Drug Information:

National Drug Code

6909-7964-53

Product Description

Vigabatrin for Oral Solution, USP 500mg/sachet

Batch Number

NB301030

Expiration Date

MARCH 2025

Company:

INVAGEN PHARMACEUTICALS INC.

QUESTIONS

Call Cipla at 844.247.5287 Monday – Friday from 8:30 a.m. to 5:00 p.m. EST or email cipla.cs@cipla.com

Vigabatrin Oral Solution

It is for this reason that we are notifying you that on 12.11.2023 the U.S. Food and Drug Administration published a drug recall for the following product(s): Vigabatrin for Oral Solution, USP 500mg/sachet.

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:

Cipla Limited announced that its wholly owned subsidiary, InvaGen Pharmaceuticals Inc. is voluntarily recalling one lot of Vigabatrin for Oral Solution, USP 500 mg, to the consumer level. The products in this lot have been found to have seal integrity issues allowing for powder leakage from the pouch.

An improper seal in the pouch may lead to the leakage of powder blend outside the pouch, resulting in a lower content of medicine inside the pouch compared to the label claim and result in potential underdosing. The population at risk is primarily infants and young children. In those patients, there is a reasonable probability that inaccurate dosing might result in a serious adverse effect such as intoxication or breakthrough seizures requiring medical intervention. To date, Cipla has not received any reports of adverse events related to this recall.

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- ext. 219. 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 Drug Recall Communication Number COM-2023-079 December 2023

pharmpix
POWERED BY ONEARK

REFERENCES:

1. U.S. Food and Drug Administration. (2023). InvaGen Pharmaceuticals Inc., InvaGen Pharmaceuticals Issues Voluntary Nationwide Recall of Vigabatrin for Oral Solution, USP 500mg due to Leaking Sachets. Retrieved December 11, 2023, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/invagen-pharmaceuticals-issues-voluntary-nationwide-recall-vigabatrin-oral-solution-usp-500mg-due
2. 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

urac ACCREDITED Pharmacy Benefit Management