Magellan Medicaid Administration

Invagen Issues Voluntary Nationwide Recall of Vigabatrin for Oral Solution, USP 500 mg Due to Leaking Sachets

Date: 12/18/2023

At Magellan Medicaid Administration, we want to help you receive the best possible care. Visit our drug recall site for details: https://www1.magellanrx.com/drug-recalls/.

About this recall:
Invagen is voluntarily recalling 1 lot of Vigabatrin for Oral Solution, USP 500 mg to the consumer level (NDC 69097-0964-53; lot NB301030; expiry 03/2025). Vigabatrin for Oral Solution, USP 500 mg has been found to have issues with the seal of the foil pouch allowing for powder leakage from the pouch. This medication is packaged in foil pouches, each containing 500 mg of Vigabatrin.

The product is used for the treatment of refractory complex partial seizures as add-on therapy in patients 2 years of age and older who have not responded adequately to several alternative treatments.

What this means to you:
If the seal on the pouch is not working, it may lead to the leakage of powder outside the pouch. This results in a lower amount of medicine inside the pouch and the potential for underdosing of the drug. The population at risk is primarily infants and young children. In those patients, the potential exists that inaccurate dosing might result in a serious adverse event (for example: breakthrough seizures) requiring medical assistance.

Invagen is coordinating the return of all recalled products. Consumers in possession of recalled Vigabatrin for Oral Solution, USP 500 mg are instructed to return the recalled drug to the place of purchase. Consumers with questions regarding this recall can contact Cipla by phone number 844-CIPLAUS (844-247-5287) Monday to Friday 8:30 AM to 5:00 PM EST, or email cipla.cs@cipla.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug.

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.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/invagen-pharmaceuticals-issues-voluntary-nationwide-recall-vigabatrin-oral-solution-usp-500mg-due

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.