Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-067-CG
December 13, 2023

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

RECOMMENDATIONS

1. InvaGen Pharmaceuticals is notifying the customer level through press releases, letters, telefax, telephone, email, and on-site visits, and is coordinating the return of all recalled products.

2. Distributors, retailers and consumers in possession of Vigabatrin for Oral Solution, USP 500mg Batch No. NB301030, NDC# 6909-7964-53 are advised to initiate the return process through their respective place of purchase.

3. Consumers with questions regarding this recall can contact Cipla by phone number 844-CIPLAUS (844-247-5287) M-F 8:30 AM-5:00 PM EST, or email cipla.cs@cipla.com.

4. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this batch of drug product.

5. Review your inventory to identify existence of recalled products.

6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

InvaGen Pharmaceuticals Issues Voluntary Nationwide Recall of Vigabatrin for Oral Solution, USP 500mg due to Leaking Sachets

Summary:

Company Announcement Date:	December 09, 2023
FDA Publish Date:	December 11, 2023
Product Type:	Drugs
Reason for Announcement:	Due to seal integrity issues allowing for powder leakage from the pouch.
Company Name:	InvaGen Pharmaceuticals Inc.
Brand Name:	No Brand
Product Description:	Vigabatrin for Oral Solution, USP 500mg

COMPANY ANNOUNCEMENT

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

Sr. No.	Product Name	NDC#	Batch No.	Expiry Date
1.	Vigabatrin for Oral Solution, USP 500mg/sachet	6909-7964-53	NB301030	03/2025

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. For a small minority of patients, who might have severe or repeated breakthrough seizures, a drop in their phenytoin blood levels could result in life-threatening seizures requiring immediate emergency room treatment. Cipla has not received any reports of adverse events related to this recall.

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The product is used for the treatment of Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded adequately to several alternative treatments. Vigabatrin for oral solution is not indicated as a first-line agent. The medication is packaged in foil pouches, each containing 500mg of Vigabatrin, and there are 50 foil sealed pouches in a shelf pack. The affected lot is NB301030, with an expiration date of 03/2025. The Vigabatrin for Oral Solution, USP 500mg product was distributed nationwide to partnered distributors and consignees.

InvaGen Pharmaceuticals is notifying the customer level through press releases, letters, telefax, telephone, email, and on-site visits, and is coordinating the return of all recalled products. Distributors, retailers and consumers in possession of Vigabatrin for Oral Solution, USP 500mg Batch No. NB301030, NDC# 6909-7964-53 are advised to initiate the return process through their respective place of purchase.

Consumers with questions regarding this recall can contact Cipla by phone number **844- CIPLAUS (844-247-5287) M-F 8:30 AM-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 this batch of 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**

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