10th December 2023

(1) BSE Limited
Listing Department,
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai 400 001

**Scrip Code: 500087**

(2) National Stock Exchange of India Limited
Listing Department
Exchange Plaza, 5th floor,
Plot no. C/1, G Block,
Bandra Kurla Complex,
Bandra (East), Mumbai - 400 051
**Scrip Code: CIPLA EQ**

(3) SOCIETE DE LA BOURSE DE LUXEMBOURG
Societe Anonyme
35A Boulevard Joseph II,
L-1840 Luxembourg

**Sub: Press Release - Voluntary Nationwide Recall of one lot of Vigabatrin for Oral Solution, USP 500mg due to leaking sachets by InvaGen Pharmaceuticals Inc., wholly owned subsidiary of the Company in USA**

Dear Sir/Madam,

Please find enclosed press release on the captioned subject.

This is for your information and records.

Thanking you,
Yours faithfully,
**For Cipla Limited**

RAJENDRA KUMAR CHOPRA
Digitally signed by RAJENDRA KUMAR CHOPRA
Date: 2023.12.10 00:23:48 +05'30'

**Rajendra Chopra**
**Company Secretary**

Encl: As above

Prepared by: Mandar Kurghode

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

Company Contact:
Name: Heena Kanal
Phone Number: +91 22 24826000

**December 09, 2023 – Hauppauge, NY:** Cipla Limited today announced that its wholly-owned subsidiary, InvaGen Pharmaceuticals Inc., USA 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.

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 also 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**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download the form at www.fda.gov/MedWatch/getforms.htm 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 U.S. Food and Drug Administration.

**DISCLAIMER**

**Cipla maintains stringent quality processes to assess quality defects and safety issues. Cipla conducts regular investigation and assessment by committees consisting of subject-matter experts, quality management, and medical safety experts.**

**For queries, please contact**:

**Corporate Communications**
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