InvaGen Pharmaceuticals – Recall of vigabatrin oral solution

- On December 11, 2023, InvaGen Pharmaceuticals (a subsidiary of Cipla) announced a consumer level recall of one lot of vigabatrin oral solution because of seal integrity issues allowing for powder leakage from the pouch.

- Vigabatrin was distributed nationwide.

Product Description	NDC#	Lot# (Expiration Date)
Vigabatrin for oral solution 500 mg/sachet	6909-7964-53	NB301030 (3/2025)

- Vigabatrin is indicated 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.

- 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.

- To date, Cipla has not received any reports of adverse events related to this recall.

- Anyone with the affected lots on hand should stop distribution and return product. Patients that have packets from the recalled lot of vigabatrin oral solution should contact their healthcare provider.

- Contact Cipla at **1- 844-247-5287** or email cipla.cs@cipla.com for questions regarding this recall.