Dec. 18, 2023

Invagen issues voluntary nationwide recall of vigabatrin for oral solution, USP 500 mg due to leaking sachets

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About this recall:

Invagen is voluntarily recalling one 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 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 at **844.CIPLAUS** (**844.247.5287**), Monday–Friday 8:30 a.m.–5 p.m. Eastern Standard Time (EST), or email **Cipla.CS@Cipla.com**. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using the recalled drug.