Endo – Expanded recall of clonazepam orally disintegrating tablets (ODT)

- On July 16, 2024, Endo announced a consumer level recall of one lot of clonazepam 0.25 mg ODT which may also appear as clonazepam 0.125 mg ODT. The recall is expanded to include the 0.125 mg strength. The recall was first announced on July 5, 2024.

- The product lot is being recalled due to mislabeling where an incorrect strength appears on the cartons of some packs to show the product strength as 0.125 mg and not 0.25 mg due to an error at a third-party packager. The blister strips inside the product pack reflect the correct strength of 0.25 mg.

- Endo shipped the recalled lot from April 2024 to June 2024.

Product Description	NDC number	Lot number (Exp Date)
Clonazepam orally disintegrating tablets, 0.125 mg	49884-306-02	550147301 (Aug 2026)
Clonazepam orally disintegrating tablets, 0.25 mg	49884-307-02	

- Clonazepam orally disintegrating tablet is useful alone or as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures. In patients with absence seizures (petit mal) who have failed to respond to succinimides, clonazepam orally disintegrating tablets may be useful. Clonazepam is also indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-V.

- Children and adults who are inadvertently prescribed a two-fold overdose of clonazepam would be at risk for the adverse effects of significant sedation, dizziness, ataxia, and confusion. There is reasonable probability for significant, possibly life-threatening, respiratory depression especially for patients with concomitant pulmonary disease, patients who have prescribed dosing near maximal dosing, and patients also taking other medications that could cause additional respiratory depression.

- To date, Endo has not received any reports of adverse events associated with this product lot recall.

- Anyone with the affected lot on hand should stop distribution and return product. Patients should not use recalled medicine and contact their healthcare provider with any medical related questions.

- Contact Inmar (appointed company for Endo) by phone at **1-877-890-0765** or email at **rxrecalls@inmar.com** for questions regarding this recall.