**Endo – Expanded recall of clonazepam orally disintegrating tablets**

- On November 18, 2024, Endo announced a voluntary, consumer level recall of many lots of clonazepam ODT tablets because of potential product carton strength mislabeling. The recall was first announced on July 5, 2024.

- Clonazepam orally disintegrating tablets were distributed nationwide between January and October 2024.

| Product Description | NDC# | Lot # (Expiration Date) |
|---|---|---|
| Clonazepam orally disintegrating tablets, 0.125 mg | 49884-306-02 | 550174101 (1/2027) |
| Clonazepam orally disintegrating tablets, 0.25 mg | 49884-307-02 | 550142801 (8/2026); 550142901 (8/2026); 550143001 (8/2026); 550143101 (8/2026); 550143201 (8/2026); 550143301 (8/2026); 550143401 (8/2026); 550147201 (8/2026); 550147401 (8/2026) |
| Clonazepam orally disintegrating tablets, 1 mg | 49884-309-02 | 550145201 (8/2026); 550145901 (2/2027); 550176001 (2/2027); 550176201 (2/2027) |
| Clonazepam orally disintegrating tablets, 2 mg | 49884-310-02 | 550176501 (2/2027); 550176601 (2/2027) |

- Clonazepam is indicated alone or as an adjunct in the treatment of the Lennoz-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures, and panic disorder.

- Children and adults who inadvertently consume a higher dose of clonazepam could be at increased risk for the adverse events of significant sedation, confusion, dizziness, diminished reflexes, ataxia, and hypotonia. 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 related to this recall.

- Anyone with the affected lots on hand should stop distribution and return product.

- Patients who have bottles from the recalled lots of clonazepam ODT should discontinue use of the product and contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

- Contact Inmar by phone at 1-855-589-1869 or email at rxrecalls@inmar.com for questions regarding this recall.