Nov. 19, 2024

Endo expands voluntary recall of clonazepam orally disintegrating tablets

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About this recall:

Endo is ***expanding*** its previously announced July 2024 voluntary recall of clonazepam orally disintegrating tablets (schedule IV controlled substance) due to potential product carton-strength mislabeling.

The manufacturer's ongoing investigation has identified the possibility that the clonazepam product lots could contain cartons printed with the incorrect strength and National Drug Code (NDC) due to an error by a third-party packager. The blister strips and tablets inside the product pack reflect the correct strength for each lot.

The expanded recall includes the following two new NDCs: 49884-0310-02 (2 mg) and 49884-0309-02 (1 mg). The expansion also includes additional lots for the two NDCs included on the initial July 2024 recall: 49884-0306-02 (0.125 mg) and 49884-0307-02 (0.25 mg). The product is packaged in cartons containing 60 tablets packed into 10 blister strips, each containing six tablets.

Clonazepam orally disintegrating tablets are indicated alone or for use as an add-on therapy for various seizure disorders (Lennox-Gastaut syndrome, akinetic and myoclonic). Additionally, the product is approved for panic disorder.

What this means to you:

Children and adults who consume a higher dose of clonazepam than planned would be at risk for the adverse events of sedation, confusion, dizziness, decreased reflexes and muscle tone, as well as problems with coordination. The potential exists for significant, possibly life-threatening, breathing problems especially in patients with lung disease, patients receiving near maximal dosing and patients taking other medications that could also cause problems breathing.

Consumers who have unused, recalled tablet cartons of clonazepam orally disintegrating tablets with the affected lot numbers **should discontinue use of the product**. If a patient took an incorrect dose rather than the intended dose, they are advised to consult a health care professional. Consumers with questions regarding this recall can contact Inmar by phone at **855.589.1869**, Monday–Friday, 9 a.m. to 5 p.m. Eastern Time (ET) or by email at **RxRecalls@Inmar.com**.