Humana

Pharmacy Solutions®

Drug recall notice for clonazepam orally disintegrating tablets

To assist you in the care of your patients, Humana is alerting you to the recall of clonazepam orally disintegrating tablets, USP (C-IV) on Nov. 18, 2024.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

The drug manufacturer, Endo USA, Inc., is voluntarily recalling these products due to potential product strength mislabeling on some cartons.

Endo expanded this previously announced recall to include additional impacted lots. Endo said in a U.S. Food and Drug Administration (FDA) drug recall notice that there is a possibility that the added clonazepam product lots could "contain a limited number of cartons printed with the incorrect strength and National Drug Code" because of an error committed by a third-party packager. The blister strips and tablets inside the cartons reflect the correct strength amount for the lot.

Clonazepam orally disintegrating tablets are indicated either alone or as an adjunct in treating Lennox-Gastaut syndrome (petit mal variant) as well as akinetic and myoclonic seizures. Clonazepam is also indicated for treatment of panic disorder. According to the FDA, children and adults inadvertently prescribed a higher dose of clonazepam are at risk for significant ataxia, confusion, diminished reflexes, dizziness, hypotonia and sedation. There also is reasonable probability for serious and even life-threatening respiratory depression, particularly for patients with concomitant pulmonary disease, patients receiving near maximal dosing and patients also taking additional medications that could cause respiratory depression, according to the FDA.

To date, Endo has received no reports of adverse events related to this recall.

Medications included in this recall
Visit the FDA website for specific details about the recalled medication.

Information for providers:[1]

- We have sent a letter to your Humana-covered patients who have had a claim for clonazepam orally disintegrating tablets and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Providers with questions can contact:
    - Inmar by phone at 877-890-0765, Monday – Friday, 9 a.m. – 5 p.m., Eastern time, or by email at rxrecalls@inmar.com
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
    - **Online:** Submit the report.
        - Select "Form FDA 3500 - Voluntary Reporting."
    - **Phone or fax:** Download the form.
        - Complete and submit "Form FDA 3500 - Voluntary Reporting" by phone at 800-FDA-1088 (332-1088) or by fax to 800-FDA-0178 (332-0178).

Reference

1. “Endo Expands Voluntary Recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) Due to Potential Product Carton Strength Mislabeling,” U.S. Food and Drug Administration, last accessed Dec. 3, 2024, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-expands-voluntary-recall-clonazepam-orally-disintegrating-tablets-usp-c-iv-due-potential.