Humana
Healthy Horizons®
in Louisiana

Drug recall notice for clonazepam orally disintegrating tablets

To assist you in the care of your patients, Humana Healthy Horizons® in Louisiana is alerting you about the recall of one lot of clonazepam 0.25 mg orally disintegrating tablets on July 16, 2024.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them about the recall.

The drug manufacturer, Endo USA, Inc., is voluntarily recalling this product for mislabeling. An incorrect strength was noted on the cartons of some packs (shown as 0.125 mg rather than 0.25 mg) because of a packaging error. The blister strips within the product pack show the correct strength of 0.25 mg.

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 U.S. Food and Drug Administration (FDA), both children and adults inadvertently prescribed a two-fold overdose of clonazepam are at risk for significant sedation, dizziness, ataxia and confusion. There also is reasonable probability for serious and even life-threatening respiratory depression, particularly for patients with concomitant pulmonary disease, patients who receive near maximal dosing and those taking additional medications that could cause respiratory depression, according to the FDA.

To date, the firm has not received any 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 sent a letter to your Humana Healthy Horizons-covered patients with claims for clonazepam 0.25 mg 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.
- 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 1-800-FDA-1088 (332-1088) or by fax to 1-800-FDA-0178 (332-0178).

Note: A reporting form also can be requested by calling 1-800-FDA-1088 (332-1088).

Reference

1. “Endo USA, Inc. Issues Voluntary, Nationwide Recall of One Lot of Clonazepam Orally Disintegrating Tablets, USP (C-IV) Lot Number 550147301 Due to Mislabeling: Incorrect Strength on Product Carton,” U.S. Food and Drug Administration, last accessed Aug. 6, 2024, www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp#:~:text=Endo%20USA%2C%20Inc.,Issues%20Voluntary%2C%20Nationwide%20Recall%20of%20One%20Lot%20of%20Clonazepam%20Orally,announcement%20as%20a%20public%20service.