Endo Issues Voluntary Nationwide Recall of One Lot of Clonazepam Orally Disintegrating Tablets

Date: 07/17/2024

About this recall:
Endo has voluntarily recalled one lot of Clonazepam Orally Disintegrating Tablets **0.25 mg**. Product may appear as Clonazepam Orally Disintegrating Tablets **0.125 mg** in a 60-count pack. The recall is to the consumer level and is due to mislabeling where an incorrect strength appears ***on the cartons*** of some packs (shown 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.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found on the following page.

Clonazepam Orally Disintegrating Tablets are indicated for use as an add-on therapy for various seizure disorders (Lennox-Gastaut syndrome, akinetic, myoclonic). Additionally, the product is approved for panic disorder. The drug is packaged in cartons of 60 tablets; the package labels include the product name, strength, lot number, and expiration date, and the National Drug Code (NDC) number 49884-0307-02; impacted units will display the NDC code 49884-0306-02.

What this means to you:
Patients who receive a two-fold overdose of clonazepam would be at risk for the adverse effects of sedation, dizziness, confusion, and problems with coordination. The potential exists for significant, possibly life-threatening, breathing problems especially in patients with lung disease, patients receiving near maximal doses, and patients taking other medications that could also cause problems breathing. To date, Endo has not received any reports of adverse events associated with this product lot recall.

Consumers who have unused, recalled 60-tablet cartons of Clonazepam Orally Disintegrating tablets, USP 0.25 mg which may also appear as Clonazepam Orally Disintegrating tablets, USP 0.125 mg with the lot number 550147301 should discontinue use of the product. If a patient took a 0.25 mg dose rather than the intended 0.125 mg dose, they are advised to consult a health care professional. Consumers with questions regarding this recall can contact Inmar by telephone at 877-890-0765 (Monday through Friday, 9 a.m. to 5 p.m. ET) or by email at rxrecalls@inmar.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntarynationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.

