DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

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

07/16/2024

MALVERN, PA, July 16, 2024 – Endo, Inc (OTCQX: NDOI) ("Endo"), announced today that one of its operating subsidiaries, Endo USA, Inc., is voluntarily recalling one lot of Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.25 mg tablets, which may also appear as Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.125 tablets 60-count pack to the consumer level.

The product lot is being recalled due to mislabeling where an incorrect strength appears on the cartons of some packs to show the product strength 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.

Risk Statement: Children and adults who are inadvertently prescribed a two-fold overdose of clonazepam would be at risk for the adverse effects of significant sedation, dizziness, ataxia, and confusion. 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 associated with this product lot recall.

Product	Lot Number	NDC	Expiration Date	Strength
Clonazepam Orally Disintegrating Tablets, USP	550147301	49884-306-02	08/2026	0.25 mg 60-count carton
Clonazepam Orally Disintegrating Tablets, USP	550147301	49884-307-02	08/2026	0.125 mg 60-count carton

Clonazepam Orally Disintegrating Tablets are indicated alone for as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures. Additionally, the product is indicated for the treatment of panic disorder. The product is packaged in cartons of 60 tablets; the package labels feature the product name, strength, lot number, and expiration date, and the National Drug Code (NDC) number 49884-307-02; impacted units will display the NDC code 49884-306-02.

This recall impacts the following product lot:

- See below image of correct carton label: Clonazepam Orally Disintegrating Tablets, USP 0.25 mg 60-count carton, lot 550147301, expiration date August 2026
- See below image of incorrect carton label: Clonazepam Orally Disintegrating Tablets, USP 0.125 mg 60-count carton, lot 550147301, expiration date August 2026

The product lot was distributed through wholesale distributors to retail pharmacies nationwide. Endo is providing written notification to wholesale accounts and retailers that have received product lot 550147301 and is arranging for the return of all existing inventory through Inmar, Inc. Distributors, retailers that have the product lot being recalled should immediately stop distributing and dispensing and return to the place of purchase or contact Inmar on the below telephone line.

Consumers in possession of any unused prescribed 60 tablet cartons of Clonazepam Orally Disintegrating tablets, USP 0.25mg which may also appear as Clonazepam Orally Disintegrating tablets USP 0.125mg bearing the lot number 550147301 have been advised to discontinue use of the product.

In the event that a patient inadvertently took a 0.25 mg dose rather than the intended 0.125 mg dose, they are advised to consult a physician

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 product lot recall is being made with the FDA’s knowledge.

About Endo
Endo is a diversified specialty pharmaceutical company boldly transforming insights into life- enhancing therapies. Our passionate team members collaborate to develop and deliver these essential medicines. Together, we are committed to helping everyone we serve live their best life. Learn more at www.endo.com or connect with us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements including any statements related to the product lot recall, adverse events, regulatory actions by the FDA and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intends," "guidance," "future," "potential" or similar expressions are forward-looking statements. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, they involve risks and uncertainties, some of which Endo may not currently be able to predict. Although Endo believes that these forward-looking statements and other information are based upon reasonable assumptions and expectations, readers should not place undue reliance on these or any other forward-looking statements and information. Actual results may differ materially and adversely from current expectations based on a number of risks, uncertainties and factors, including risks and uncertainties related to the recall and any future recalls, potential adverse events and any regulatory actions by the FDA. Endo assumes no obligation to publicly update any forward- looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

Contacts:
Media:
Linda Huss
media.relations@endo.com

Investors:
Laure Park
investor.relations@endo.com

Company Contact Information

Consumers:

Inmar, Inc.

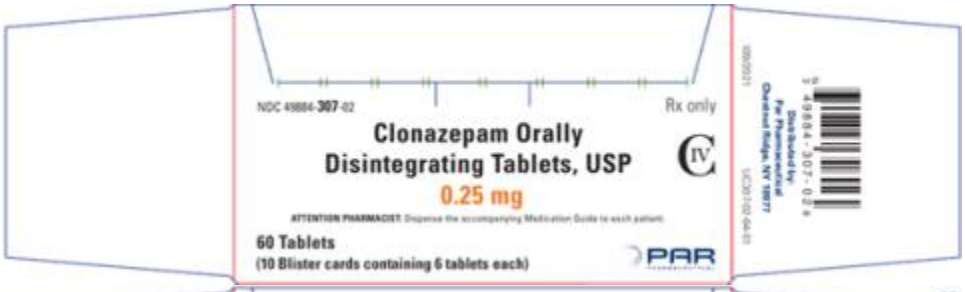
1-855-410-3565

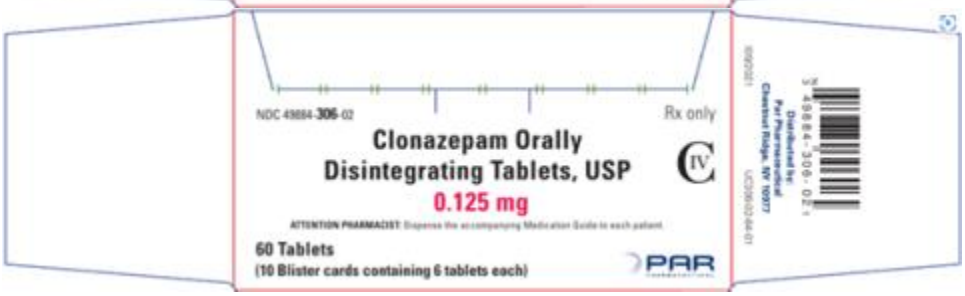
Media:

Linda Huss

media.relations@endo.com

Product Photos:

- 

- 

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp?utm_medium=email&utm_source=govdelivery