Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-035-CG
July 23, 2024

FDA announced that 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.

RECOMMENDATIONS

1. 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.
2. 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.
3. 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
4. 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.
5. Review your inventory to identify existence of recalled products.
6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

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

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SUMMARY:

Company Announcement Date:	July 16, 2024
FDA Publish Date:	July 17, 2024
Product Type:	Drugs
Reason for Announcement:	Mislabeled with the incorrect strength on the carton
Company Name:	Endo USA, Inc
Brand Name:	Par Pharmaceutical
Product Description:	Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.25 mg tablets

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COMPANY ANNOUNCEMENT:

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.

Clonazepam Orally Disintegrating Tablets are indicated alone for as an adjunct in the treatment of the Lennoz-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures. Additionally, the

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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

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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**

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