Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-049-CG
November 22, 2024

FDA announced that, Endo, Inc. (OTCQX: NDOI) ("Endo") announced today that one of its operating subsidiaries, Endo USA, Inc., is expanding its previously announced voluntary recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) due to potential product carton strength mislabeling.

RECOMMENDATIONS

1. The product lots were distributed through wholesale distributors to retail pharmacies nationwide.
2. Endo is providing written notification to wholesale accounts and retailers that have received the product lots and is arranging for the return of all existing inventory through Inmar, Inc.
3. 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.
4. Consumers in possession of any unused prescribed tablet cartons of Clonazepam Orally Disintegrating tablets, USP bearing the above lot numbers have been advised to discontinue use of the product.
5. In the event that a patient inadvertently took an incorrect dose rather than the intended dose, they are advised to consult a physician.
6. Consumers with questions regarding this recall can contact Inmar by telephone at 855-589- 1869 (Monday through Friday, 9 a.m. to 5 p.m. ET) or by email at rxrecalls@inmar.com.
7. Review your inventory to identify existence of recalled products.
8. 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

Bionpharma Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension Due to Bacterial Contamination

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SUMMARY:

Company Announcement Date:	September 17, 2024
FDA Publish Date:	September 18, 2024
Product Type:	Drugs
Reason for Announcement:	Product found to be contaminated with Cohnella bacteria
Company Name:	Bionpharma Inc.
Brand Name:	Bionpharma
Product Description:	Atovaquone Oral Suspension, 750 mg/mL

COMPANY ANNOUNCEMENT:

Endo, Inc. (OTCQX: NDOI) ("Endo") announced today that one of its operating subsidiaries, Endo USA, Inc., is expanding its previously announced voluntary recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) due to potential product carton strength mislabeling.

Specifically, Endo's ongoing investigation has identified the possibility that the Clonazepam product lots listed below contain a limited number of cartons printed with the incorrect strength and National Drug Code (NDC) code due to an error by a third-party packager. The blister strips and tablets inside the product pack reflect the correct strength for the lot.

The following table details the lots being added to the voluntary recall, including lot product description and NDC number.

Potential Product Description / NDC Number	Lot #
Clonazepam ODT, USP (C-IV) 2mg / 49884-310-02	550176501
	550176601
Clonazepam ODT, USP (C-IV) 0.125mg / 49884-306-02	550174101

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Potential Product Description / NDC Number	Lot #
Clonazepam ODT, USP (C-IV) 0.25mg / 49884-307-02	550142801
	550142901
	550143001
	550143101
	550143201
	550143301
	550143401
	550147201
	550147401
Clonazepam ODT, USP (C-IV) 1mg / 49884-309-02	550145201
	550175901
	550176001
	550176201

RISK STATEMENT:

Children and adults who inadvertently consume a higher dose of clonazepam could be at increased risk for the adverse events of significant sedation, confusion, dizziness, diminished reflexes, ataxia, and hypotonia. 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 recall.

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

PACKAGE IDENTIFICATION:

The product is packaged in cartons containing 60 tablets packed into 10 blister strips each containing 6 tablets. The carton and each blister strip pocket are printed with the name, strength, lot number, expiration date, and NDC number. The packaging lists the legacy company Par Pharmaceutical which previously marketed clonazepam before the product was acquired by Endo. The images below provide an example of the potential mislabeling showing the components of a package of Clonazepam Orally Disintegrating tablets, USP 2 mg lot 550176501 with a carton bearing the product description and NDC code of Clonazepam Orally Disintegrating Tablets, USP 1 mg 60-count. The location of the lot number on each component of the package is shown on the photographs below.

Carton front and blister pack:

ACTION REQUIRED:

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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 tablet cartons of Clonazepam Orally Disintegrating tablets, USP bearing the above lot numbers have been advised to discontinue use of the product.

In the event that a patient inadvertently took an incorrect dose rather than the intended dose, they are advised to consult a physician.

Consumers with questions regarding this recall can contact Inmar by telephone at 855-589- 1869 (Monday through Friday, 9 a.m. to 5 p.m. ET) or by email at rxrecalls@inmar.com.

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For more information about Clonazepam Orally Disintegrating Tablets, USP, please see full Prescribing Information including BOXED WARNING available at DailyMed - CLONAZEPAM tablet, orally disintegrating (nih.gov).

Adverse reactions or quality problems experienced with the use of this product lot may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm
- Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm
- Fax: **1-800-FDA-0178**

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