COMMUNICATION

COM-2024-076

21 NOVEMBER 2024

URGENT PLEASE REVIEW

# Recall Notification

## PharmPix Clinical Department


PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

## U.S. Food & Drug Administration Publication Date:

11/19/2024

## Drug Information:

### National Drug Code

Refer to the table included in the notification

### Product Description

Clonazepam Orally Disintegrating Tablets, USP (C-IV)

### Lot Numbers

Refer to the table included in the notification

### Expiration Date

February 2027

## Company:

Endo, Inc.

### QUESTIONS

Call Endo, Inc. at 1-800-828-9393

Call Inmar, Inc. (Distributor) at 855-589-1869 Monday – Friday from 9 a.m. to 5 p.m ET

## Clonazepam Orally Disintegrating Tablets

It is for this reason that we are notifying you that on 11/19/2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Clonazepam Orally Disintegrating Tablets, USP (C-IV).

### Pharmacy Required Action:

**Identify** if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

**Advise** patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

### Reason for Recall:

Endo, Inc. is expanding its previously announced voluntary recall of Clonazepam ODT, USP (C-IV) due to potential product carton strength mislabeling.

Specifically, Endo's investigation has identified the possibility that the Clonazepam product lots listed in this notification contain a number of cartons printed with the incorrect strength and NDC due to an error by a third-party packager. The product is packaged in cartons containing 60 tablets packed into 10 blister strips each containing 6 tablets.

### Risk Statement:

Patients 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.

Recalled Lots:

| Product | Presentation | NDC | Lot Number | Expiration Date |
|---|---|---|---|---|
| Clonazepam ODT, USP (C-IV) | 2mg | 49884-310-02 | 550176501 | February 2027 |
| | | | 550176601 | |
| Clonazepam ODT, USP (C-IV) | 0.125mg | 49884-306-02 | 550174101 | |
| 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 | |

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

**PharmPix Drug Recall Communication** Number COM-2024-076 November 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Endo Expands Voluntary Recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) Due to Potential Product Carton Strength Mislabeling. Retrieved November 20, 2024, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-expands-voluntary-recall-clonazepam-orally-disintegrating-tablets-usp-c-iv-due-potential
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda


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