COMMUNICATION

COM-2024-048

18
July
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:

7/17/2024

Drug Information:

National Drug Code

49884-306-02

Product Description:

Clonazepam Orally Disintegrating Tablets 0.25mg, 60-count carton

Lot Number

550147301

Expiration Date

August 2026

Company:

Endo USA, Inc

QUESTIONS

Call Inmar Inc at 877-890-0765 (Monday - Friday, 9:00 am – 5:00 pm ET) or by email at rxrecalls@inmar.com.

Clonazepam Orally Disintegrating Tablets 0.25mg

It is for this reason that we are notifying you that on 07.17.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Clonazepam Orally Disintegrating Tablets 0.25mg, 60-count carton.

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: 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.

CLINICAL PEARLS
BY PHARMPIX

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-2024-048 July 2024

pharmpix
POWERED BY ONEARK

REFERENCES:

1. U.S. Food and Drug Administration. (2024). 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. Retrieved July 17, 2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp
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

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
FRM-CL-000126-001

CLINICAL PEARLS BY PHARMPIX