July 17, 2024

Endo issues voluntary nationwide recall of 1 lot of clonazepam orally disintegrating tablets

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About this recall:

Endo has voluntarily recalled one lot of clonazepam orally disintegrating tablets 0.25 mg. Product may appear as clonazepam orally disintegrating tablets 0.125 mg in a 60-count pack. The recall is to the consumer level and is due to mislabeling where an incorrect strength appears on the cartons of some packs (shown 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.

Clonazepam orally disintegrating tablets are indicated for use as an add-on therapy for various seizure disorders (Lennox-Gastaut syndrome, akinetic, myoclonic). Additionally, the product is approved for panic disorder. The drug is packaged in cartons of 60 tablets; the package labels include the product name, strength, lot number, and expiration date, and the National Drug Code (NDC) 49884-0307-02; impacted units will display NDC 49884-0306-02

What this means to you:

Patients who receive a two-fold overdose of clonazepam would be at risk for the adverse effects of sedation, dizziness, confusion and problems with coordination. The potential exists for significant, possibly life-threatening, breathing problems especially in patients with lung disease, patients receiving near maximal doses and patients taking other medications that could also cause problems breathing. To date, Endo has not received any reports of adverse events associated with this product lot recall.

Consumers who have unused, recalled 60-tablet cartons of clonazepam orally disintegrating tablets, USP 0.25 mg, which may also appear as clonazepam orally disintegrating tablets, USP 0.125 mg with the lot number 550147301, should discontinue use of the product. If a patient took a 0.25 mg dose rather than the intended 0.125 mg dose, they are advised to consult a health care professional. Consumers with questions regarding this recall can contact Inmar by phone at **877.890.0765**, Monday–Friday, 9 a.m. to 5 p.m. Eastern Standard Time (EST) or by email at **RxRecalls@Inmar.com**.