COMMUNICATION

COM-2023-034

15
JUNE
2023

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:

06.14.2023

Drug Information:

National Drug Code

Refer to the table included in the notification.

Product Description

Dronabinol Capsules USP 2.5mg

Ziprasidone HCl Capsules 20mg

Lot Number

Refer to the table included in the notification.

Expiration Date

Refer to the table included in the notification.

Company:

Harvard Drug Group, LLC

QUESTIONS

Call Sedgwick at 1.888.759.6904 Monday – Friday from 8:00 a.m. to 5:00 p.m. ET or by email address harvarddrug6068@sedgwick.com

Dronabinol and Ziprasidone.

It is for this reason that we are notifying you that on 06.14.2023 the US Food and Drug Administration published a drug recall for the following product(s): Dronabinol Capsules USP 2.5mg and Ziprasidone Hydrochloride Capsules 20mg.

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 Harvard Drug Group initiated a voluntary recall of a single lot of Dronabinol Capsules USP 2.5mg and Ziprasidone Hydrochloride Capsules 20mg to the consumer level. The company received a customer complaint that some unit dose cartons labeled as Ziprasidone Hydrochloride Capsules 20mg were found to contain blister packages labeled as and containing Dronabinol Capsules USP 2.5mg for Lot T04769.

Patients who mistakenly take dronabinol instead of ziprasidone can experience serious adverse events from missing their ziprasidone dose and taking an unexpected dose of dronabinol. Patients missing doses of ziprasidone can experience exacerbation of underlying health issues, resulting in mental illness instability.

Reason for Recall (continuation):

On the other hand, taking an unexpected dose of dronabinol may cause mental and cognitive effects that result in impairment of mental and/or physical abilities. Elderly patients or those taking other medications that affect mental function may be particularly at risk for these reactions. The company has not received any reports of adverse events related to this recall.

Product Name	Package Description	Lot Number	NDC	Expiration Date
Dronabinol Capsules USP 2.5mg	100-unit doses per carton (10 x 10 blister packs)	T04769	0904-7144-61	2024/12
Ziprasidone Hydrochloride Capsules 20mg	40-unit doses per carton (10 x 4 blister packs)	T04769	0904-6269-08	2024/12

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- Clinical Department. 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-2023-034 June 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). The Harvard Drug Group, LLC Issues Voluntary Nationwide Recall of Dronabinol Capsules, USP, 2.5 mg and Ziprasidone Hydrochloride Capsules, 20 mg Due to Label Mix-up. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/harvard-drug-group-llc-issues-voluntary-nationwide-recall-dronabinol-capsules-usp-25-mg-and
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda