Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-033-CG
June 16, 2023

FDA announced that, Harvard Drug Group, LLC d/b/a Major Pharmaceutical and Rugby Laboratories is initiating a voluntary recall of a single lot of Dronabinol Capsules, USP, 2.5 mg and Ziprasidone Hydrochloride Capsules, 20 mg to the consumer level. The Harvard Drug Group, LLC received a customer complaint from a distributor that some unit dose cartons labeled as Ziprasidone Hydrochloride Capsules, 20 mg were found to contain blister packages labeled as and containing Dronabinol Capsules, USP, 2.5 mg for Lot T04769. Accordingly, The Harvard Drug Group, LLC is recalling all of Lot T04769, Dronabinol Capsules, USP, 2.5 mg, which may be in outer cartons that read Dronabinol Capsules, USP, 2.5 mg OR Ziprasidone Hydrochloride Capsules, 20 mg.

RECOMMENDATIONS

1. The Harvard Drug Group, LLC is notifying all impacted direct accounts via mail of this voluntary recall and is arranging for return of all recalled products listed above. Wholesalers, Distributors and Retailers that have the affected product which is being recalled should stop distribution of the product and consumers should stop using this affected product, return it to the place of purchase, and contact their physician or healthcare provider.

2. Consumers with questions regarding this recall can contact Sedgwick, Inc. by phone at 1-888-759-6904 (8:00am-5:00pm EST Monday through Friday) or by email address harvarddrug6068@sedgwick.com.

3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.Review your inventory to identify existence of recalled products.

4. 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

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FDA U.S. FOOD & DRUG ADMINISTRATION

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

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Summary:

Company Announcement Date:	June 13, 2023
FDA Publish Date:	June 14, 2023
Product Type:	Drugs
Reason for Announcement:	Packaging may contain incorrect product due to labeling mix-up
Company Name:	The Harvard Drug Group, LLC d/b/a Major Pharmaceutical and Rugby Laboratories
Brand Name:	Major Pharmaceuticals
Product Description:	Dronabinol Capsules 2.5mg and Ziprasidone Hydrochloride Capsules 20mg

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Company Announcement

FOR IMMEDIATE RELEASE – June 13, 2023 – La Vergne, TN, The Harvard Drug Group, LLC d/b/a Major Pharmaceutical and Rugby Laboratories is initiating a voluntary recall of a single lot of Dronabinol Capsules, USP, 2.5 mg and Ziprasidone Hydrochloride Capsules, 20 mg to the consumer level. The Harvard Drug Group, LLC received a customer complaint from a distributor, that some unit dose cartons labeled as Ziprasidone Hydrochloride Capsules, 20 mg were found to contain blister packages labeled as and containing Dronabinol Capsules, USP, 2.5 mg for Lot T04769. Accordingly, The Harvard Drug Group, LLC is recalling all of Lot T04769, Dronabinol Capsules, USP, 2.5 mg, which may be in outer cartons that read Dronabinol Capsules, USP, 2.5 mg OR Ziprasidone Hydrochloride Capsules, 20 mg.

Risk Statement: There is a reasonable probability that patients who mistakenly take Dronabinol Capsules, USP, 2.5 mg instead of Ziprasidone Hydrochloride, 20 mg capsules, can experience serious adverse events from 1) missing their ziprasidone dose and 2) taking an unexpected dose of Dronabinol. Patients missing doses of Ziprasidone can experience exacerbation of underlying health issues such as bipolar disorder, schizophrenia, agitation, aggression, or delirium. This can result in mental illness instability with possible consequences of self-harm or harm to others which could result in medical or psychiatric hospitalization. Taking an unexpected dose of Dronabinol

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may cause mental and cognitive effects that result in impairment of mental and/or physical abilities. This can include worsening of symptoms in patients with mental illness disorders and limitation of patients' abilities to safely complete hazardous activities (e.g., driving a motor vehicle, operating machinery). Elderly patients or those taking other medications that affect mental function may be particularly at risk for these reactions. The Harvard Drug Group, LLC has not received any reports of adverse events related to this recall.

Ziprasidone Hydrochloride Capsules, 20 mg, is used for the treatment of schizophrenia, as monotherapy for the acute treatment of bipolar manic or mixed episodes, and as an adjunct to lithium or valproate for the maintenance treatment of bipolar disorder.

Dronabinol Capsules, USP, 2.5 mg, is used as: (1) an anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS), and (2) Nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Both Ziprasidone Hydrochloride Capsules, 20 mg and Dronabinol Capsules, USP, 2.5 mg are labeled with lot T04769 EXP. 2024/12 and can be identified on the outer carton labeling as follows:

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

Ziprasidone Hydrochloride Capsules, 20 mg are capsules with a lavender opaque cap and flesh opaque body, imprinted "RDY' on the cap and "356" on the body.

Dronabinol Capsules, USP, 2.5 mg are white capsules imprinted with "M2."
Images of the outer carton labeling of both Ziprasidone Hydrochloride Capsules, 20 mg and Dronabinol Capsules, USP, 2.5 mg and in addition, images of the blister packages of Dronabinol Capsules, USP, 2.5 mg found in cartons labeled as Ziprasidone Hydrochloride Capsules, 20 mg, can be found below.

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Products were distributed Nationwide to Wholesalers starting April 5, 2023.

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Consumers with questions regarding this recall can contact Sedgwick, Inc. by phone at 1-888-759-6904 (8:00 am - 5:00 pm EST Monday through Friday) or by email address harvarddrug6068@sedgwick.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form 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

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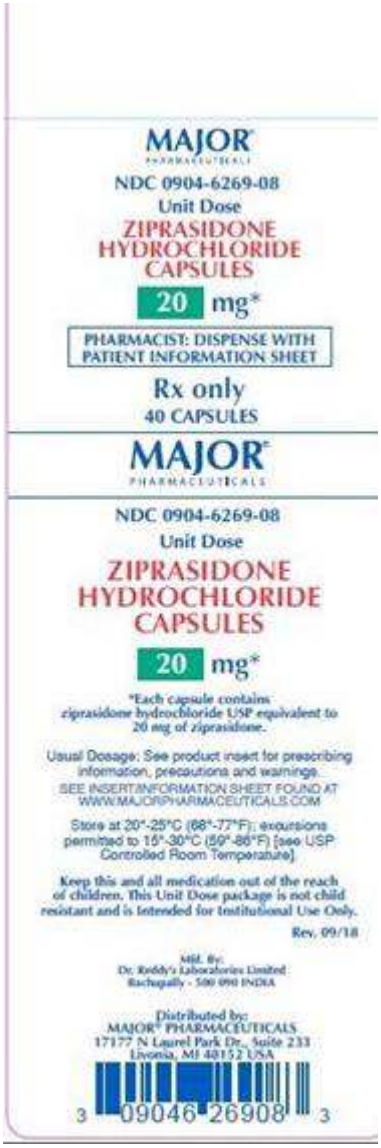

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