June 14, 2023

The Harvard Drug Group 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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The Harvard Drug Group has posted a lot recall of dronabinol capsules 2.5 mg and ziprasidone hydrochloride capsules 20 mg.

About this recall:

The Harvard Drug Group 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 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 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.

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 immunodeficiency deficiency syndrome (AIDS), and (2) nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments

What this means to you:

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 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). Older patients or those taking other medications that affect mental function may be particularly at risk for these reactions. The Harvard Drug Group has not received any reports of adverse events related to this recall.

Consumers with questions regarding this recall can contact Sedgwick, Inc. by phone at **888.759.6904**, Monday–Friday, 8:00 a.m.–5 p.m. Eastern Standard Time (EST) or by email at **HarvardDrug6068@Dedgwick.com**. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product