Major and Rugby – Recall of dronabinol and ziprasidone

- On June 14, 2023 the FDA announced a consumer level recall of a single lot of Major Pharmaceutical's and Rugby Laboratories' dronabinol capsules and ziprasidone capsules. Some unit dose cartons labeled as ziprasidone 20 mg capsules were found to contain blister packages labeled as and containing dronabinol 2.5 mg capsules. Dronabinol 2.5 mg capsules may be in outer cartons that read dronabinol or ziprasidone.

Product Description	Lot Number (Exp Date)	NDC Number
Dronabinol 2.5 mg capsules, 100 unit doses per carton (10 x 10 blister packs)	T04769 (12/2024)	0904-7144-61
Ziprasidone 20 mg capsules, 40 unit doses per carton (10 x 4 blister packs)	T04769 (12/2024)	0904-6269-08

- Ziprasidone 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 is used for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS), and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.
- There is a reasonable probability that 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 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).
- Elderly patients or those taking other medications that affect mental function may be particularly at risk for these reactions.
- To date, the Harvard Drug Group has not received any reports of adverse events related to this recall.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug products.
- Anyone with the affected lot on hand should stop use and distribution and return to place of purchase.

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- Contact Sedgwick at **1-888-759-6904** or by email at **harvarddrug6068@sedgwick.com** for questions regarding this recall.

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