COMMUNICATION

COM-2023-045

01
AUGUST
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:

07.31.2023

Drug Information:

National Drug Code

Refer to the table included in the notification.

Product Description

TYDEMY™ (DROSPIRENONE, ETHINYL ESTRADIOL AND LEVOMEFOLATE CALCIUM 3MG/0.03MG/0.451MG AND LEVOMEFOLATE CALCIUM 0.451MG) TABLETS

Lot Number

Refer to the table included in the notification.

Expiration Date

Refer to the table included in the notification.

Company:

LUPIN PHARMACEUTICALS, INC.

QUESTIONS

Call INMAR RX SOLUTIONS, INC. at 1.866.480.8206 Monday – Friday from 9:00 a.m. to 5:00 p.m. ET.

Tydemy™ Oral Contraceptive

It is for this reason that we are notifying you that on 7.31.2023 the US Food and Drug Administration published a drug recall for the following product(s): Tydemy™ 3mg/0.03mg/0.451mg-0.451mg

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:

Lupin Pharmaceuticals, Inc. is voluntarily recalling two lots of Tydemy™ (drospirenone, ethinyl estradiol and levomefolate calcium tablets 3mg/0.03mg/0.451mg and levomefolate calcium tablets 0.451mg) to the patient level due to out of specification test results at the 12-month stability time point. One of the lots (L200183) tested low for ascorbic acid (inactive ingredient) and high for a known impurity.

Lupin is recalling two batches because if there is a possibility that there is a low amount of the inactive ingredient, it could potentially impact the effectiveness of the product resulting in unexpected pregnancy.

To date, Lupin has received no reports of adverse events related to either recalled batches.

Recalled Lots:

Product	Lot Number	Expiry Date	NDC(s)	Distribution Dates
Tydemy™	L200183	January 2024	68180-904-71 (1 blister of 28 tablets each) 68180-904-73 (3 blisters of 28 tablets each)	June 2022 to May 2023
	L201560	September 2024		

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-2023-045 August 2023

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urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

REFERENCES:

1. U.S. Food and Drug Administration. (2023). Lupin Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of 2 Lots of TydemyTM (Drospirenone, Ethinyl Estradiol and Levomefolate Calcium Tablets 3mg/0.03mg/0.451mg and Levomefolate Calcium Tablets 0.451mg) Due to Out of Specification (OOS) Results at the 12-month Stability Time Point. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-2-lots-tydemytm-drospirenone-ethinyl
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