COMMUNICATION

COM-2023-052

01
SEPTEMBER
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:

08.31.2023

Drug Information:

National Drug Code

Refer to the list included in this notification.

Product Description

Refer to the list included in this notification.

Batch Number

Refer to the list included in this notification.

Expiration Date

FEBRUARY 2025

Company:

MARLEX PHARMACEUTICALS, INC.

QUESTIONS

Call MARLEX PHARMACEUTICALS, INC. at 302.328.3355 or toll free 888.582.1953 Monday – Friday from 8:30 a.m. to 4:30 p.m. CDT.

Digoxin Tablets

It is for this reason that we are notifying you that on 08.31.2023 the US Food and Drug Administration published a drug recall for the following product(s): Digoxin tablets USP, 0.125mg and Digoxin Tablets USP, 0.25mg.

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:

Marlex Pharmaceuticals, Inc. is voluntarily recalling one lot of Digoxin Tablets USP, 0.125mg and one lot of Digoxin Tablets USP, 0.25mg to the consumer level due to label mix-up.

The bottles of the Digoxin Tablets, USP 0.125mg are incorrectly labeled and contain Digoxin Tablets USP, 0.25mg. The bottles of Digoxin Tablets USP, 0.25mg are incorrectly labeled and contain Digoxin Tablets USP, 0.125mg.

This label mix-up can potentially cause either overdosing or underdosing in patients who unknowingly take the wrong dose.

Marlex Pharmaceuticals, Inc. has not received any reports of adverse events related to this recall.

Reason for Recall:

The product is packaged as 100 tablets in white HDPE bottles and labeled as indicated below with the NDC, lot number and expiration date.

- Digoxin 0.125mg Tablet: NDC 10135-0747-01, lot # E3810, expiration 02/2025
- Digoxin 0.25mg Tablet: NDC 10135-0748-01, lot # E3811, expiration 02/2025

The products were distributed nationwide. Marlex Pharmaceuticals, Inc. is notifying its distributors and customers by email and is arranging for return of all recalled products.

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-2023-052 September 2023

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urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

REFERENCES:

1. U.S. Food and Drug Administration. (2023). Marlex Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Digoxin Tablets USP, 0.125mg and Digoxin Tablets USP, 0.25mg Due to Label Mix-Up.https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marlex-pharmaceuticals-inc-issues-voluntary-nationwide-recall-digoxin-tablets-usp-0125mg-and-digoxin
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