Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-047-CG
September 1st, 2023

FDA announced that 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. Bottles of Digoxin Tablets, USP 0.125mg s are incorrectly labeled and contain Digoxin Tablets USP, 0.25mg Tablets. Bottles of Digoxin Tablets USP, 0.25mg are incorrectly labeled and contain Digoxin Tablets USP, 0.125mg.

RECOMMENDATIONS

1. Consumers/distributors/retailers that have Digoxin Tablets USP, 0.125mg and Digoxin Tablets USP, 0.25mg (lot# E3810 and lot# E3811) which are being recalled should stop using/return to place of purchase. Marlex Pharmaceuticals, Inc. is notifying its distributors and customers by emails and is arranging for return of all recalled products (lot# E3810 and lot# E3811).

2. Consumers with questions regarding this recall can contact Marlex Pharmaceuticals, Inc. by phone number 302-328-3355 or toll free 888-582-1953 on Monday - Friday from 8.30AM and 4:30PM, EST.

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.

4. Review your inventory to identify existence of recalled products.

5. 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

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Marlex Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Digoxin Tablets USP, 0.125mg and Digoxin Tablets USP, 0.25mg Due to Label Mix-Up

Summary:

Company Announcement Date:	August 30, 2023
FDA Publish Date:	August 31, 2023
Product Type:	Drugs
Reason for Announcement:	Label Mix-Up
Company Name:	Marlex Pharmaceuticals, Inc.
Brand Name:	Marlex Pharmaceuticals, Inc.
Product Description:	Digoxin Tablets USP, 0.125mg and 0.25mg

Company Announcement

FOR IMMEDIATE RELEASE – August 30, 2023 – New Castle, Delaware, 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. Bottles of Digoxin Tablets, USP 0.125mg s are incorrectly labeled and contain Digoxin Tablets USP, 0.25mg Tablets. Bottles of Digoxin Tablets USP, 0.25mg are incorrectly labeled and contain Digoxin Tablets USP, 0.125mg.

Digoxin Tablets USP, 0.125mg are yellow, circular, beveled, uncoated tablets scored between "N" and "201" on one side and plain on the other side.

Digoxin Tablets USP, 0.25mg are white to off-white, circular. beveled, uncoated tablets scored between "N" and "202" on one side and plain on the other side.

Risk Statement: The mix-up in labels can cause either overdosing or underdosing in patients who unknowingly take the wrong dose. Patients who intend to take Digoxin Tablets USP, 0.125mg, but unknowingly Digoxin 0.25mg would receive a super potent dose and can experience significant drug toxicity (mental disorientation, dizziness, blurred vision, memory loss and fainting) from the unintentional overdose. Patients who intend to take Digoxin Tablets USP, 0.25mg, but unknowingly take Digoxin 0.125mg would receive a sub potent dose which may lead to loss of control of heart rate and potential heart failure exacerbation. Marlex Pharmaceuticals, Inc has not received any reports of adverse events related to this recall.

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The product is used for the treatment of mild to moderate heart failure. Digoxin increases heart muscle contraction in pediatric patients with heart failure. Digoxin is indicated for the control of ventricular response rate in adult patients with chronic atrial fibrillation. The product is packaged as 100 tablets in white HDPE bottles and labeled as indicated below with NDC, lot and expiration date.

> Digoxin 0.125mg Tablet – NDC 10135-0747-01, lot# E3810, expiration 2/2025
> Digoxin 0.25mg Tablet – NDC 10135-0748-01, lot# E3811, expiration 2/2025
> Digoxin Tablets USP, 0.125mg and Digoxin Tablets USP, 0.25mg Product were distributed Nationwide.

Consumers/distributors/retailers that have **Digoxin Tablets USP, 0.125mg and Digoxin Tablets USP, 0.25mg (lot# E3810 and lot# E3811)** which are being recalled should **stop using/return to place of purchase**. Marlex Pharmaceuticals, Inc. is notifying its distributors and customers by emails and is arranging for **return** of all recalled products **(lot# E3810 and lot# E3811)**.

Consumers with questions regarding this recall can contact Marlex Pharmaceuticals, Inc. by phone number 302-328-3355 or toll free 888-582-1953 on Monday - Friday from 8.30AM and 4:30PM, EST. 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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