

FDA Drug Recall

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

8/30/2023

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.

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 <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>
- Regular Mail or Fax: <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting> 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Marlex Pharmaceuticals, Inc
302-328-3355 or toll free 888-582-1953

Product Photos



Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marlex-pharmaceuticals-inc-issues-voluntary-nationwide-recall-digoxin-tablets-usp-0125mg-and-digoxin?utm_medium=email&utm_source=govdelivery