COMMUNICATION

COM-2023-015

28
MARCH
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:

03/22/2023

Drug Information:

National Drug Code

Refer to table included in the notification.

Product Description

DABIGATRAN ETEXILATE MESYLATE CAPSULES, USP 75MG AND 150MG

Lot Number

Refer to table included in the notification.

Expiration Date

Refer to table included in the notification.

Company:

Ascend Laboratories LLC.

QUESTIONS

Call Ascend Laboratories, LLC. at 877-272-7901, 24 hours, 7 days a week.

Dabigatran Etexilate Mesylate Capsules

It is for this reason that we are notifying you that on 03/22/2023 the US Food and Drug Administration published a drug recall for the following product(s): Dabigatran etexilate mesylate 75mg and 150mg capsules.

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:

Ascend Laboratories LLC. is voluntarily recalling dabigatran etexilate mesylate capsules, USP 75mg and 150mg to the consumer level due to the presence of a nitrosamine. N-nitroso-dabigatran was above the established Acceptable Daily Intake level. Nitrosamines are common in water and foods. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. To date, Ascend Laboratories LLC. has not received any reports of adverse events related to this recall.

Wholesalers/distributors and pharmacies with an existing inventory of the recalled products should stop use and distribution and quarantine the product immediately.

The product lots were distributed nationwide to wholesalers, distributors, and retailers in the United States from June 2022 to October 2022.

Product	NDC	Lot Number	Expiration Date	Configuration/Count
Dabigatran etexilate mesylate capsules 150mg	67877-475-60	22142448	May 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 150mg	67877-475-60	22142449	May 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 150mg	67877-475-60	22142450	May 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 75 mg	67877-474-60	22142462	May 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 75 mg	67877-474-60	22142463	May 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 75 mg	67877-474-60	22142464	May 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 75 mg	67877-474-60	22143000	June 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 75 mg	67877-474-60	22143001	June 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 75 mg	67877-474-60	22143002	June 2024	60 capsules/bottle
Dabigatran etexilate mesylate capsules 150mg	67877-475-60	22143845	July 2024	60 capsules/bottle

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.

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urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

REFERENCES:
1. U.S. Food and Drug Administration. (2023). Ascend Laboratories LLC. Issues Voluntary Nationwide Recall of Dabigatran Etexilate Capsules, USP 75 mg and 150 mg, Due to the Detection of N-Nitroso-dabigatran (NDAB) Impurity. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg
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