Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-018-CG
March 24, 2023

FDA announced that Ascend Laboratories LLC. is voluntarily recalling Dabigatran Etexilate Capsules. USP 75 mg and 150 mg to the consumer/user level due to the presence of a nitrosamine. N-nitroso-dabigatran, above the established Acceptable Daily Intake (ADI) level. To date, Ascend Laboratories LLC., has not received any reports of adverse events related to this recall.

RECOMMENDATIONS

1. Wholesalers/distributors and pharmacies with an existing inventory of the lots listed, should stop use and distribution and quarantine the product immediately.

2. Wholesalers and Distributors are advised to recall the distributed product. Please notify any accounts or additional locations that may have received the recalled product from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Ascend requests that they immediately cease distribution of the affected product.

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. Consumers with questions regarding this recall can contact Ascend Laboratories LLC. Using the below information, **877-272-7901**, 24 hrs, 7 days a week, to report adverse events and product complaints.

5. Review your inventory to identify the existence of recalled products.

6. 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
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FDA U.S. FOOD & DRUG ADMINISTRATION

Ascend Laboratories LLC. Issues Voluntary Nationwide Recall of Dabigatran Etexilate Capsules, USP 75 mg and 150 mg, Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

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Summary:

Company Announcement Date:	March 22, 2023
FDA Publish Date:	March 22, 2023
Product Type:	Drugs
Reason for Announcement:	Detection of N-Nitrosodimethylamine (NDMA) Impurity
Company Name:	Ascend Laboratories LLC.
Brand Name:	Ascend Laboratories
Product Description:	Dabigatran Etexilate Capsules, USP

Company Announcement

FOR IMMEDIATE RELEASE- Parsippany. New Jersey. Ascend Laboratories LLC. is voluntarily recalling Dabigatran Etexilate Capsules. USP 75 mg and 150 mg to the consumer/user level due to the presence of a nitrosamine. N-nitroso-dabigatran, above the established Acceptable Daily Intake (ADI) level. To date, Ascend Laboratories LLC., has not received any reports of adverse events related to this recall.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

The product is used as an oral anticoagulant to lower the risk of stroke and blood clots.

The NDC. Lot Number. Expiration Date. and Packaging Configuration details for Dabigatran Etexilate Capsules that are subjected to this recall are indicated in the table below. The product lots were distributed nationwide to wholesalers, Distributors and Retailers (dispensers) in the United States from June 2022 to October 2022.

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Product	NDC	Lot Number	Expiration Date	Presentation	Configuration /Count
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22142448	MAY.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22142449	MAY.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22142450	MAY.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22142462	MAY.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22142463	MAY.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22142464	MAY.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22143000	JUN.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22143001	JUN.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 75 Mg	67877-474-60	22143002	JUN.2024	HDPE Bottles	60 capsules/bottle
Dabigatran Etexilate Mesylate Caps 150 Mg	67877-475-60	22143845	JUL.2024	HDPE Bottles	60 capsules/bottle

Wholesalers/distributors and pharmacies with an existing inventory of the lots listed in the table above, should stop use and distribution and quarantine the product immediately.

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Patients who have received impacted lots of Dabigatran Etexilate Capsules, USP 75 mg and 150 mg are advised to continue taking their medication and contact their physician for advice regarding an alternative treatment.

Consumers with questions regarding this recall can contact Ascend Laboratories LLC. using the information below.

Contact Center	Contact Information	Area of Support
Ascend Laboratories, LLC	877-272-7901, 24 hrs., 7 days a week	To report adverse events and product complaints

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.

Customers with medical-related questions, who wish to report an adverse event, or quality issues about the products being recalled should contact **Ascend Laboratories LLC., by phone at: 877- 272-7901, 24 hrs, 7 days a week.**

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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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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