ASCEND

URGENT: DRUG RECALL

Hindy Schiff, Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
339 Jefferson Road, Suite 101
Parsippany, NJ, 07054

December 5, 2024

Dear Customer:

This is to inform you of a product recall involving Dabigatran Etexilate Mesylate (EM) Capsules, 75 and 150 mg. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed
1	Dabigatran EM Capsules	24142192	150 mg	April 2026	60 capsules/ bottle	67877-475-60	September 17, 2024	3,097
2	Dabigatran EM Capsules	24142193	150 mg	April 2026	60 capsules/ Bottle	67877-475-60	July 16, 2024	2,078
3	Dabigatran EM Capsules	24142194	150 mg	April 2026	60 capsules/ Bottle	67877-475-60	July 24, 2024	3,828
4	Dabigatran EM Capsules	24142463	150 mg	May 2026	60 capsules/ Bottle	67877-475-60	July 16, 2024	1,801
5	Dabigatran EM Capsules	24142328	75 mg	May 2026	60 capsules/ Bottle	67877-474-60	August 9, 2024	97
6	Dabigatran EM Capsules	24142329	75 mg	May 2026	60 capsules/ Bottle	67877-474-60	July 24, 2024	73
7	Dabigatran EM Capsules	24142330	75 mg	May 2026	60 capsules/ bottle	67877-474-60	August 26, 2024	1,441
Total Distributed								12,415

See enclosed product label for ease in identifying the product at the RETAIL level.

An out-of-specification (OOS) result was observed during the analysis of Dabigatran Etexilate Mesylate Capsules (150 mg), Batch # 24142462. The observed level of the N-nitroso-dabigatran impurity was found to be 1.48 ppm, exceeding the specified limit of not more than (NMT) 1.33 ppm. As part of the impact assessment, other batches which are within the shelf life were analyzed, including stability-incubated products and finished product batches for different strengths (75 mg, 110 mg, and 150 mg). The analysis identified a total of six OOS findings.

Dabigatran is in a class of anticoagulant medications called direct thrombin inhibitors. Dabigatran is used to decrease the risk of stroke and blood clots in patients with a serious heart rhythm problem called nonvalvular atrial fibrillation. Dabigatran is also used to treat and prevent blood clots (e.g., deep vein thrombosis, pulmonary embolism) from occurring again in patients who already have received other medicines. It is also used to prevent deep vein thrombosis and pulmonary embolism after hip replacement surgery. It works by preventing harmful clots from forming in the blood vessels.

Long-term ingestion of N-nitrosodabigatran may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication.

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.

Our firm began shipping this product on July 16, 2024. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above.

Please perform the following activities:

a. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above. Please follow the directions in the attached recall stock response to return the affected product.

b. Promptly identify your recall customer(s) who received the recall product and provide them with clear instructions to return the recall product.
c. Promptly complete the attached recall stock response form even if you have no product to return.
d. The completed Recall Response Form can be submitted by any of the following methods:

Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

This recall is being carried out to the RETAIL level. Your assistance is appreciated and necessary to prevent consumer harm.

Your assistance is appreciated and necessary in this voluntary recall. If you have any questions related to customer service, please contact product inquiries—available 24 hours a day, 7 days a week—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 866-792-8407—available 9:00 AM to 5:00 PM ET Monday through Friday.

For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax:

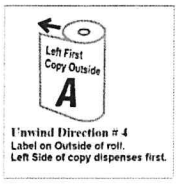
1. Complete and submit the report Online: www.fda.gov/medwatch/report.htm
2. Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178.

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

Sincerely,

Hindy Schiff

Vice President, Regulatory Affairs and Compliance



Unwind Direction # 4
Label on Outside of roll.
Left Side of copy dispenses first.

GTIN :
S / N :
EXP :
LOT :

For batch details & 2D code

Each capsule contains 86.48 mg dabigatran etexilate mesylate equivalent to 75 mg dabigatran etexilate.

Contains FD&C Yellow No.6 as a color additive.

Usual Dosage: See package insert for dosage information.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Store in the original package in order to protect from moisture.

Keep the bottle tightly closed.

Keep out of reach of children.

Manufactured by: Alkem Laboratories Ltd., INDIA.

Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054

ASCEND Laboratories, LLC

NDC 67877-474-60

Dabigatran Etexilate Capsules

75 mg

Swallow capsule whole.

Once opened, the product must be used within 4 months.

DISPENSE IN THIS UNIT OF USE CONTAINER WITH ENCLOSED MEDICATION GUIDE

Rx Only **60 Capsules**

Unvarnished area
40 x 30 mm (LXH)
Rest label should be
with UV Varnish

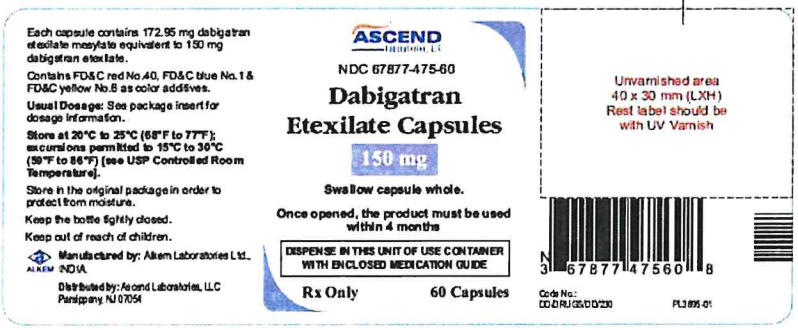
N 3 67877 47460 1

Code No.:
DD/DRUGS/DD/230 PL3894

Alkem Laboratories Limited

Product: Dabigatran Etexilate Caps 75 mg		Market: Ascend, US	Size: (L x H) 125 x 50 mm
Itemcode: PL3894	Version No: 00	Superseed No: NA	Mfg Location: Amaliya
Pantone No: Pantone Blue 072 C, Pantone 171 C, Pantone 285 C, Pantone 2725 C, Black			Pack Size: 60's
Component: Label	Style: Roll form	Substrate: 80 gsm chromo paper/20 gsm Hot-melt adhesive/65gsm release paper	
Change Part No: NA		Pharmacode: 1256	Barcode: N367877474601
Reason for Issue: For Commercialization (3)			Change Control No:
Date of Initiation: 31/07/2014			Final Approval of artwork:
Modification Date: 10-02-2022	*Space between two labels should NMT 10 mm		

1256



Alkem Laboratories Limited			
Product: Dabigatran Etexilate Caps 150 mg		Market: Ascend, US	Size: (L x H) 125 x 50 mm
Itemcode: PL3895-01	Version No: 01	Superseed No: PL3895	Mfg Location: Amaliya
Pantone No.: Pantone Blue 072 C Pantone 171 C Pantone 285 C Pantone 2725 C Black			Pack Size: 60's
Component: Label	Style: Roll form	Substrate: 80 gsm chromo paper/20 gsm Hot-melt adhesive/65gsm release paper	
Change Part No: NA		Pharmacode: 3301	Barcode: N367877475608
Reason for Issue: Text change (1)			Change Control No: Q/CC/P/2022/0348 PR ID - 86506
Date of Initiation: 17-06-2022			Final Approval of artwork:
Modification Date:		*Space between two labels should NMT 10 mm	

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RECALL STOCK RESPONSE FORM

Recall-Dabigatran EM Tablets, 75 mg and 150 mg

Lot Numbers: 24142192, 24142193, 24142194, 24142463, 24142328, 24142329, 24142330

Customer Name: _____ DEA #:_____

Please note that DEA # is required. If it is not provided, the processing of your form will be delayed.

Address:_____

City:_____ State:_____ Zip Code:_____

Contact Name (please print): _____Telephone #:_____

Contact Signature: _____ Date:_____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____Wholesaler DEA#:_____

Wholesaler City:_____ Wholesaler State:_____ Wholesaler Zip: _____

Please check and fill out EACH section accordingly.

☐ I have read and understand the recall instructions provided in the Recall Letter.

☐ I have checked my stock for the quarantined inventory indicated in the table below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Quantity on Hand
1	Dabigatran EM Capsules	24142192	150 mg	April 2026	60 capsules/ bottle	67877-475-60	
2	Dabigatran EM Capsules	24142193	150 mg	April 2026	60 capsules/ Bottle	67877-475-60	
3	Dabigatran EM Capsules	24142194	150 mg	April 2026	60 capsules/ Bottle	67877-475-60	
4	Dabigatran EM Capsules	24142463	150 mg	May 2026	60 capsules/ Bottle	67877-475-60	
5	Dabigatran EM Capsules	24142328	75 mg	May 2026	60 capsules/ Bottle	67877-474-60	
6	Dabigatran EM Capsules	24142329	75 mg	May 2026	60 capsules/ Bottle	67877-474-60	
7	Dabigatran EM Capsules	24142330	75 mg	May 2026	60 capsules/ bottle	67877-474-60	

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Indicate disposition of recalled product:

□ returned (specify quantity, date and method)/held for return:

_____

_____

□ destroyed (specify quantity, date and method):

_____

_____

□ relabeled (specify quantity and date):

_____

_____

□ quarantined pending correction (specify quantity):

_____

_____

□ transfused – Blood or blood products (specify date and quantity):

_____

_____

□ implanted (specify date and quantity):

_____

_____

□ I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification):

_____

_____

If you have any questions regarding this form or product return, please contact Inmar at 1-866-792-8407. Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.

Please return this form by fax to 1-817-868-5362 or E-mail rxrecalls@inmar.com.

After receipt of this response form, a return kit will be provided for affected product return to:

Inmar Rx Solutions

3845 Grand Lakes Way

Grand Prairie, TX, 75050

Inmar Recall Event ID: RCL282-2024