July 17, 2023

URGENT: DRUG RECALL

This is to inform you of a product recall involving:

Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed
Fingolimod Capsules	22122841	0.5 mg	August 2025	30's HDPE Bottle Pack	67877-476-30	September 2022	79,560 capsules

See enclosed product label for ease in identifying the product.

This recall has been initiated due to an out of specification result observed in dissolution testing and due to numerous market complaints received related to receipt of broken capsules. This voluntary recall is being initiated as a precautionary measure involving Fingolimod Capsules 0.5 mg, lot number 22122841.

Under the knowledge of the Food and Drug Administration, this recall should be conducted to the retail level (Class II).

Please perform the following activities:

a. Immediately examine your inventory and quarantine product subject to recall for the lot number specified in the table above.

b. Please 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.

The completed Recall Response Form can be submitted by any of the below methods:

Fax: 817-868-5362

E-mail: rxrecalls@inmar.com

Your assistance is appreciated and necessary in this voluntary recall. If you have any question related to customer service, please contact product inquiries—available 24 hours a day—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 833-599-3217.

Sincerely,

Hindy Schiff

Vice President, Regulatory Affairs/Compliance

RECALL STOCK RESPONSE FORM

Recall – Fingolimod Capsules

Level II – Retail

Please fill out this form completely. By doing so, this will acknowledge that you have read and understood the recall instructions and have taken appropriate action.

Customer Name: _____ DEA #: _____

*Please note 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 Code: _____

I have checked my stock and:

_____ Do not have any of the recalled items.

OR

I have quarantined and listed in the box below the quantity of recall units, and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar will issue a return authorization label (s). Please indicate the number of required box labels: _____

I confirm that all locations that have received impacted product have been notified to the wholesale level.

Initial _____ Date: _____

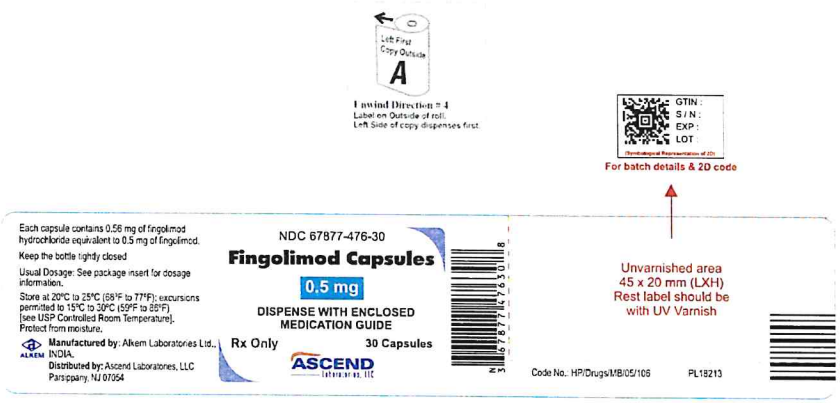
Please see the table below and indicate the amount of product you have on hand in the appropriate column/row of the table.

Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity on Hand for Return
Fingolimod Capsules	22122841	0.5 mg	August 2025	30's HDPE Bottle Pack	67877-476-30	September 2022	

If you have any questions regarding this form or product return, please contact Inmar at 833-599-3217, Office Hours: 9:00 AM to 5:00 PM CT Monday through Friday.

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

APPROVED



Alkem Laboratories Limited			
Product: Fingolimod Caps 0.5mg		Market: Ascend, US	Size: (L x H) 115 x 25 mm
Itemcode: PL18213	Version No: 00	Superseed No: NA	Mfg Location: Baddi
Pantone No.: Pantone Blue 072 C Pantone 171 C Pantone 285 C Pantone 2725 C Black			Pack Size: 30's
Component: Sticker Label	Style: Roll form	Substrate: 80 gsm chromo paper/20 gsm Hot-melt adhesive/65gsm release paper	
Change Part No: NA		Pharmacode: 3347	Barcode: N367877476308
Reason for Issue: For Commercial			Change Control No: Q/CC/P/2022/0485 PR ID - 93981
Date of Initiation: 30/08/2022			Final Approval of artwork:
Modification Date:			

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