URGENT: DRUG RECALL

Clindamycin Phosphate Foam 1%

100 g (Can)

Topical Foam (NDC 68462-605-94)

September 10, 2026

Dear Pharmacy, Wholesale, and Retail Customers:

This is to inform you that Glenmark is initiating a voluntary recall at the Retail level involving the following prescription product.

Clindamycin Phosphate foam 1% 100 g

Sr. No	NDC	Batch Number	Pack Size	Expiry Date
1	68462-605-94	14240600	100 gm	Nov-26
2	68462-605-94	14250040	100 gm	Dec-26
3	68462-605-94	14250207	100 gm	Apr-27
4	68462-605-94	14250213	100 gm	Apr-27
5	68462-605-94	14250363	100 gm	Jul-27

Glenmark is initiating a recall at the Retail level for the above-identified batches of Clindamycin Phosphate foam 1%.

Clindamycin Phosphate Foam 1% is a topical lincosamide indicated for the topical treatment of acne vulgaris. The product is supplied as a white thermolabile hydroethanolic aerosol foam containing 1% clindamycin (as clindamycin phosphate) in a pressurized aluminium aerosol can.

Glenmark submitted the initial Field Alert Report (FAR) on August 20, 2026, to notify the Agency of a market complaint (CH-2026014335-00) received for Clindamycin Phosphate Foam, 1% (100 g), regarding a damaged and leaking product. During the investigation, a protocol-driven leak test study was performed on reserve samples comprising eleven (11) cans from each of the five commercial batches (14250207 – complaint batch, 14250213, 14250363, 14250040 and 14240600) of Clindamycin

Phosphate Foam, 1% (100 g), as part of the impact assessment. The study, conducted on August 18, 2026, identified product leakage in reserve samples from each of the five batches.

As of today, only one (1) market complaint has been received regarding leakage of the product.

A Health Hazard Assessment (HHA) was conducted in response to the reported complaint and concluded that the observed product quality defect is unlikely to pose a clinically significant risk to patient health or safety. This determination was based on the detectability of the defect (container leakage), the absence of patient exposure due to non-use of the affected product, and the lack of reported adverse events associated with the issue.

Although the HHA identified no significant impact on patient health or safety, Glenmark is initiating a voluntary retail-level recall of the five (5) affected batches distributed in the U.S. market as a precautionary measure.

Please examine your inventory, and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA initiated shipment of this product on February 12, 2025.

In addition, if you are a wholesaler/ distributor, who has further distributed this product, please identify those retail customers and notify them at once of this Product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter. Again, this recall should be carried out to the retail level only. Because this is not a consumer level recall, notice to the consumer level is not required.

Glenmark is requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your recall return packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your recall return, please contact Inmar at **888-270-0963**.

Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

thomas.callaghan@glenmarkpharma.com
thomas.callaghan@glenmarkpharma.com
2026.09.10 10:34:06 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

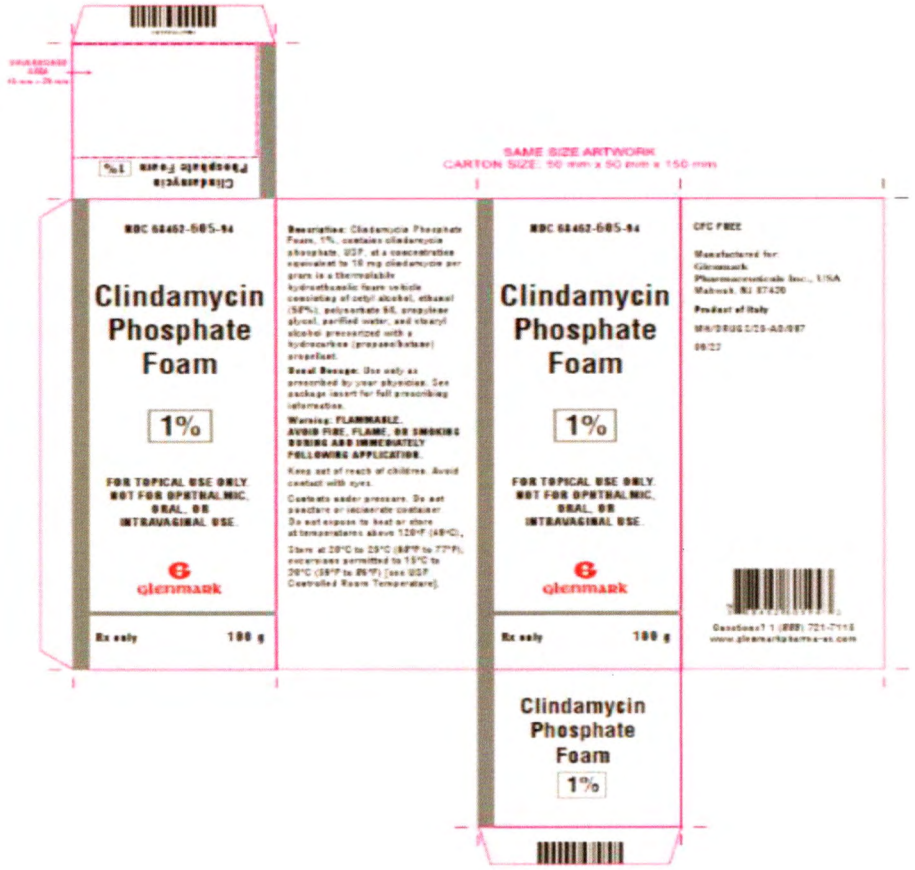
US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall Return Response Form


NDC 68462-605-94
Clindamycin Phosphate Foam
1%
FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.
Glenmark
Rx only
100 g
CFC FREE
Description: Clindamycin Phosphate Foam, 1%, contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram in a thermolabile hydroethanolic foam vehicle consisting of cetyl alcohol, ethanol (68%), polysorbate 60, propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon (propane/butane) propellant.
Usual Dosage: Use only as prescribed by your physician. See package insert for full prescribing information.
Warning: FLAMMABLE. AVOID FIRE, FLAME, OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.
Keep out of reach of children. Avoid contact with eyes.
Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).
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].
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
Product of Italy
MK/DRUGS/25-AD/097
09/22
PBSS1710923-1
Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com
UNVARNISHED AREA FOR LOT AND EXP
85 mm
135 mm


SAME SIZE ARTWORK
NDC 68462-685-94
Clindamycin Phosphate Foam
1%
FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.
glenmark
Rx only
100 g
Description: Clindamycin Phosphate Foam, 1%, contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram in a thermolabile hydroethanolic foam vehicle consisting of cetyl alcohol, ethanol (58%), polysorbate 60, propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon (propane/butane) propellant.
Usual Dosage: Use only as prescribed by your physician. See package insert for full prescribing information.
Warning: FLAMMABLE. AVOID FIRE, FLAME, OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.
Keep out of reach of children. Avoid contact with eyes.
Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).
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].
CFC FREE
Manufactured for:
Glenmark
Pharmaceuticals Inc., USA
Mahwah, NJ 07430
Product of Italy
MM/DRUG/C/0-AD/007
06/22

Can Label


85 mm
NDC 68462-605-94
Clindamycin Phosphate Foam
1%
FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.
Glenmark
Rx only
100 g
CFC FREE
Description: Clindamycin Phosphate Foam, 1%, contains clindamycin phosphate, USP, at a concentration equivalent to 10 mg clindamycin per gram in a thermolabile hydroethanolic foam vehicle consisting of cetyl alcohol, ethanol (58%), polysorbate 60, propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon (propane/butane) propellant.
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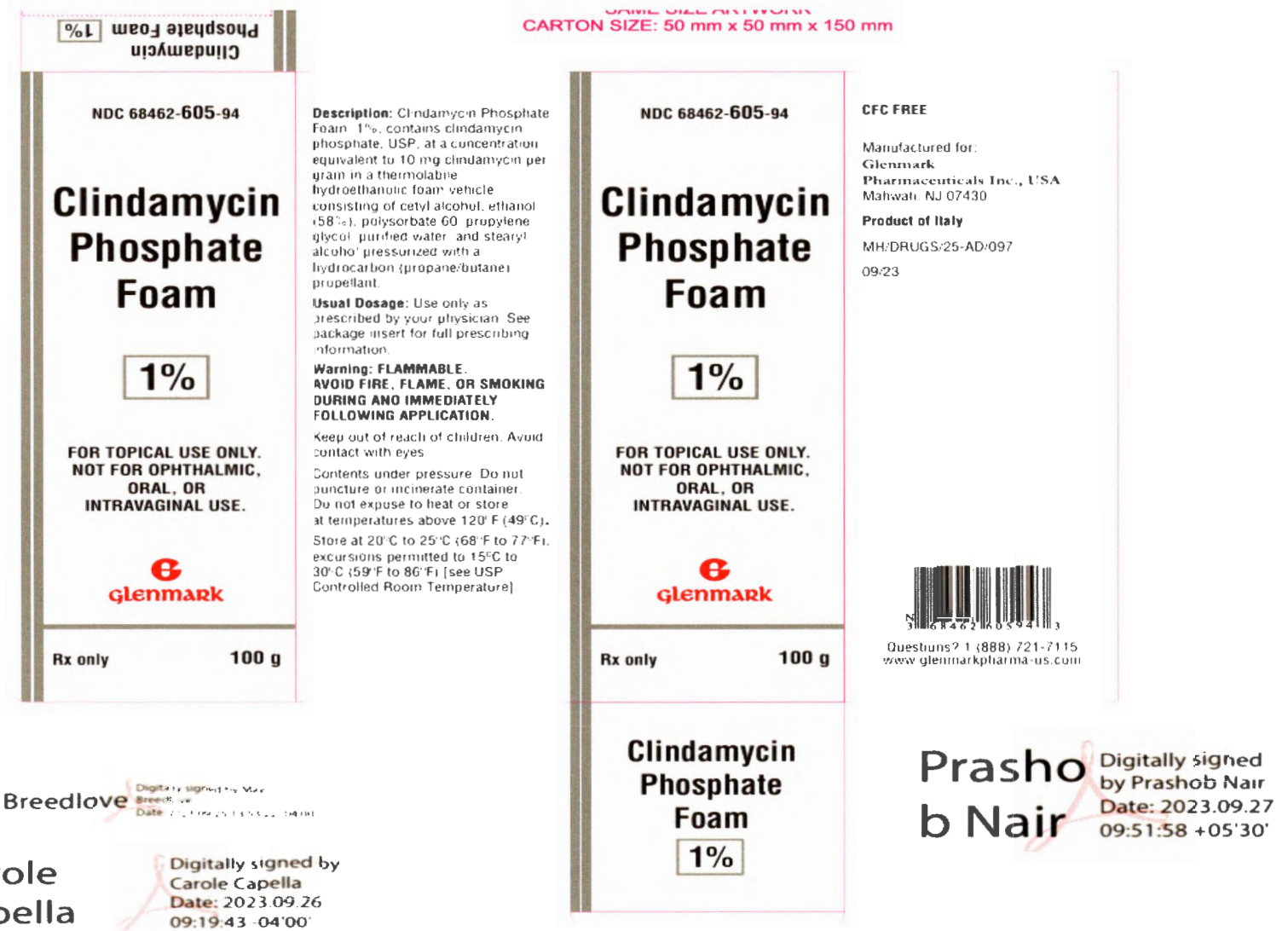
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
Product of Italy
MH/DRUGS/25-AD/097
09/23
N 3 68462 60594 3
Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com
PE651710923-1

Carton Label



May Breedlove

Carole Capella
Digitally signed by Carole Capella
Date: 2023.09.26 09:19:43 -04'00'

Prashob Nair
Digitally signed by Prashob Nair
Date: 2023.09.27 09:51:58 +05'30'

Glenmark Pharmaceuticals Inc.

RECALL RETURN RESPONSE FORM

Clindamycin Phosphate Foam 1%

100 g

(NDC 68462-605-94)

Retail Level

9/10/2026

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

Customer Name:	DEA#:

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	
DEBIT MEMO# (If unsure, leave blank):		

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:	
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

□ I confirm that all locations that received the impacted products have been notified to the Retail level _____(Initial and date)

□ I do not have any stock of the recall 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 return authorization label(s) Please indicate the # of needed box labels_____.

Recall Event ID N131524 RCL271-26

Clindamycin Phosphate foam 1% 100 g

Sr. No.	Item Description	NDC#	Lot#	Exp. Date	Total Full/ Sealed and Partial/ Open Can Count
1	Clindamycin Phosphate foam 1% 100 g	68462-605-94	14240600	November-2026	
2	Clindamycin Phosphate foam 1% 100 g	68462-605-94	14250040	December-2026	
3	Clindamycin Phosphate foam 1% 100 g	68462-605-94	14250207	April-2027	
4	Clindamycin Phosphate foam 1% 100 g	68462-605-94	14250213	April-2027	
5	Clindamycin Phosphate foam 1% 100 g	68462-605-94	14250363	July-2027	

If you have any questions regarding this form or product return, please contact Inmar at 888-270-0963.

Office hours are 9 AM to 5 PM EST, Mon through Fri.

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

RECALL EVENT ID- N131524 RCL271-26