



October 29, 2024

URGENT DRUG RECALL

Dear Customer:

This official communication is to notify you that Viona Pharmaceuticals Inc. (“Viona”), is voluntarily recalling drug product mentioned in the table below at the **RETAIL LEVEL:**

Product	NDC Number	Lot Number	Expiry Date	Count	Distribution Start Date	Distribution End Date
Dapsone Gel 7.5%	72578-094-02	T401151	06/2026	60 g Airless pump pack	08/31/2024	09/06/2024
Dapsone Gel 7.5%	72578-094-02	T400806	03/2026	60 g Airless pump pack	07/03/2024	07/29/2024

Due to repetitive market complaints observed in drug product Dapsone Gel 7.5% for batch number T401151, T400806, regarding “gritty / grainy texture” of the product, Viona advises its customers that have this product in stock to discontinue use/dispense/distribution of these lots and return it to Inmar Rx Solutions as per the details below.

Through this communication, we request you organize the return of the above-referenced drug product in your possession. To facilitate this recall, please complete the following actions:

1. Examine your available stock as per the above-mentioned product and lot numbers. If you have the concerned lot numbers of the drug product in your stock, please discontinue further distribution, quarantine the affected product and return all units to Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050. A credit memo will be issued covering the quantity of your return to Inmar Rx Solutions.
2. Please complete the enclosed “PRODUCT RECALL RESPONSE FORM” and fax it to us at 1-817-868-5362 or email it to rxrecalls@inmar.com. Even if you do not possess any inventory of the lot being recalled, we would appreciate it if you could still fill out and return the “PRODUCT RECALL RESPONSE FORM”.

Please complete and return the enclosed response form as soon as possible.

Viona Pharmaceuticals Inc.

20 Commerce Drive, Ste 340, Cranford, NJ 07016

Phone: +1 908 956 0600 *Fax: +1 908 514 4005 *www.vionausa.com



If you have any questions about the logistics for returning affected lots or other issues, please call Recall Services at 1-855-558-1554 during business hours Monday – Friday (excluding holidays), 9 am to 5 pm EST.

If you have any questions about product safety concerns, then please call Viona Drug Safety/Medical Affairs at 1-888-304-5011 during business hours Monday – Friday (excluding holidays), 9 am to 5 pm EST.

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

We apologize for any inconvenience this voluntary recall may have caused you. Your assistance is appreciated and necessary to prevent further product usage.

Sincerely,

**Prakash
Rajendran**

Digitally signed by
Prakash Rajendran
Date: 2024.10.29
16:47:00 -04'00'

Prakash Rajendran
Sr. Manager – Regulatory Affairs
Viona Pharmaceuticals Inc.

20 Commerce Drive, Ste 340, Cranford, NJ 07016

Phone: +1 908 956 0600

Fax: +1 908 514 4005



Dapsone Gel 7.5%, Bottle Label

NDC 72578-094-02

Dapsone Gel

7.5%

FOR TOPICAL USE ONLY

 **60 g**
Rx only

FOR TOPICAL USE ONLY: Not for oral, ophthalmic, or intravaginal use.
Usual dosage: Apply once daily. See package insert for complete prescribing information.
WARNING: Keep this and all drugs out of the reach of children.
Each gram of gel contains 75 mg of dapsone USP.
Inactive ingredients: diethylene glycol monoethyl ether, methylparaben, acrylamide/sodium acryloyldimethyl taurate copolymer, isohexadecane, polysorbate 80 and purified water.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. **Protect from freezing.**
GUJ/DRUGS/G/25/1919
Manufactured by: Zydus Lifesciences Ltd.
Ahmedabad, India
Distributed by: Viona Pharmaceuticals Inc.
Cranford, NJ 07016

Rev.: 06/23
2093195



20 Commerce Drive, Ste 340, Cranford, NJ 07016

Phone: +1 908 956 0600

Fax: +1 908 514 4005



Dapsone Gel 7.5%, Carton Label



20 Commerce Drive, Ste 340, Cranford, NJ 07016

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Fax: +1 908 514 4005



PRODUCT RECALL RESPONSE FORM
URGENT DRUG RECALL - RETAIL

Please complete the required information and fax it to **1-817-868-5362**
or email to rxrecalls@inmar.com

To the Attention of Drug Safety/ Recall Services-Viona Pharmaceuticals Inc.

Product Detail	NDC Number	Lot No.	Exp Date	No. of Bottle Purchased	No of the Bottles consumed	No. of bottles in Possession	No of Bottles to be returned
Dapsone Gel 7.5%	72578-094-02	T401151	06/2026				
Dapsone Gel 7.5%	72578-094-02	T400806	03/2026				

No. of Returns kit required: _____

Please mark as applicable

☐ We currently do not have any inventory of the above-listed Lot/bottles

☐ We are notifying our customers

☐ We have identified and notified my customers that were shipped or may have been shipped this product by _____;

☐ Attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product? ☐ Yes ☐ No

If yes, please explain:

Viona Pharmaceuticals Inc.

20 Commerce Drive, Ste 340, Cranford, NJ 07016

Phone: +1 908 956 0600 *Fax: +1 908 514 4005 *www.vionausa.com



Please check appropriate box to describe your business

☐ Wholesaler/Distributor

☐ Retailers

☐ Repackager

☐ Manufacturer

☐ Pharmacy- Retail

☐ Hospital/ Medical Facility

☐ Hospital Pharmacies

☐ Medical Laboratory

☐ Other: _____

Name: _____

Title: _____

Tel Number: _____

Firm Name: _____

DEA# _____

Address: _____

City/ State: _____

If you have not purchased, the concerned lot directly from Viona Pharmaceuticals Inc., then
please provide details of your wholesaler: _____ (Name, City)

DEA# _____

Signature: _____

Date: _____

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