



December 10, 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:**

S. No	Product Detail	NDC Number	Lot Number	Expiry Date	Count	Distribution Start Date	Distribution End Date
1.	Dapsone Gel 7.5%	72578-094-03	T400514	02/2026	90 g Airless pump pack	7/3/2024	10/8/2024
2.	Dapsone Gel 7.5%	72578-094-03	T400808	03/2026	90 g Airless pump pack	10/2/2024	11/20/2024
3.	Dapsone Gel 7.5%	72578-094-02	T400513	02/2026	60 g Airless pump pack	11/20/2024	7/3/2024
4.	Dapsone Gel 7.5%	72578-094-02	T400807	03/2026	60 g Airless pump pack	7/30/2024	8/20/2024
5.	Dapsone Gel 7.5%	72578-094-02	T401152	06/2026	60 g Airless pump pack	8/20/2024	9/19/2024
6.	Dapsone Gel 7.5%	72578-094-02	T401303	07/2026	60 g Airless pump pack	9/19/2024	10/8/2024
7.	Dapsone Gel 7.5%	72578-094-02	T401304	07/2026	60 g Airless pump pack	10/8/2024	10/25/2024
8.	Dapsone Gel 7.5%	72578-094-02	T401399	07/2026	60 g Airless pump pack	10/25/2024	11/22/2024
9.	Dapsone Gel 7.5%	72578-094-02	T401696	08/2026	60 g Airless pump pack	11/22/2024	11/27/2024

Due to repetitive market complaints observed in drug product Dapsone Gel 7.5% regarding “gritty / grainy texture” of the product, as a precautionary measure and an immediate action, Viona advises its customers that have the above mentioned lot(s) of the said product in stock to discontinue use/dispense/distribution of these lots and return it to Inmar Rx Solutions as per the details below.

Viona Pharmaceuticals Inc.

20 Commerce Drive, Ste 340, Cranford, NJ 07016

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



VIONA

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.

If you have any questions about the logistics for returning affected lots or other issues, please call Recall Services at 1-877-442-8747 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
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%, 90g Bottle Label

NDC 72578-094-03

**Dapsone
Gel**

7.5%

FOR TOPICAL USE 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
2093196

3 72578 09403 4

 **90 g**
Rx only

20 Commerce Drive, Ste 340, Cranford, NJ 07016

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Dapsone Gel 7.5%, 90g Carton Label



20 Commerce Drive, Ste 340, Cranford, NJ 07016
Phone: +1 908 956 0600
Fax: +1 908 514 4005



Dapsone Gel 7.5%, 60g 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
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Ahmedabad, India
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