

Emily Madsen
Director of Quality Management
Omeza, LLC
1610 Northgate Blvd
Sarasota, Florida 34234
1/19/24

Subject: **URGENT DRUG PRODUCT RECALL** – Omeza Lidocaine Lavage and Omeza Skin Protectant

The purpose of this letter is to advise you that Omeza, LLC is voluntarily recalling two lots of **Lidocaine Lavage** and one lot of **Skin Protectant**.

Lidocaine Lavage

Intended use statement: for the temporary relief of pain and itching.

Skin Protectant:

Intended use statement: temporarily protects minor cuts, scrapes, or burns.

These products were manufactured in a facility that was not in full compliance with current good manufacturing practice requirements. Testing on the products indicates that these manufacturing conditions did not affect the safety of the products. There have also been no reports of adverse events attributed to any of the products being recalled. In an abundance of caution, however, Omeza, LLC is recalling the products. The affected lot numbers and expiration dates are provided in the table below.

Brand Name	Part Number	Lot Number	Expiration Date(s)	Distribution Dates
Omeza Lidocaine Lavage	859839007434	28622 2-1	04/24/24	11/21/22 to 8/21/23
Omeza Lidocaine Lavage	859839007434	28622 2-3	1/25/24 or 4/25/24	9/20/23 to 12/13/23
Omeza Skin Protectant	859839007632	19123 4-1	5/11/2024	10/17/23 to 12/29/23

OCM™ (wound matrix) is not affected by this recall.

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to recall. Immediately discontinue use and distribution of the identified lot numbers. A refund will be issued covering the quantity of your product returned.
2. If you may have further distributed this product, please identify those customers and notify them at once of this product recall. Your notification to your customers should include a copy of this recall notification letter and the response form.
3. Please complete and return a copy of the enclosed “Customer Recall Return Response Form” as soon as possible to Omeza by email to customerservice@omeza.com.
4. Contact Omeza Customer Service at 888-886-6392 to obtain a pre-printed, pre-paid return label.
5. Return products to:
Omeza, LLC
ATTN: Customer Service

1610 Northgate Blvd
Sarasota, FL 34234

This recall should be carried out to the **user level**.

This recall is being made with the knowledge of and in cooperation with the U.S. Food and Drug Administration (FDA).

We sincerely apologize for any inconvenience this may cause and appreciate your cooperation in this matter. If you have any questions or require further information, please contact our Customer Service at 888-886-6392, M-F 8:30am-5pm EST.

Thank you for your immediate attention to this matter.

Sincerely,

Emily Madsen
Director of Quality Management
emadsen@omeza.com
860-597-3966

CUSTOMER RECALL RETURN RESPONSE FORM

Acknowledgement and Receipt Form

Response is required

Please check all appropriate boxes.

I have read and understand the recall instructions provided in the attached letter.

I have checked my stock and have quarantined the following inventory.

Brand Name	Lot Number	Expiration Date(s)	Quantity Held for Return
Omeza Lidocaine Lavage	28622 2-1	04/24/24	
Omeza Lidocaine Lavage	28622 2-3	1/25/24 or 4/25/24	
Omeza Skin Protectant	19123 4-1	5/11/2024	

I am a distributor and I have identified and notified my customers who were shipped this product by providing each a copy of the Recall Letter and this Form.

DATE: _____ Method of Notification: Email Other _____.

Attached is a list of customers who received this product and the quantities they received.

Any adverse events associated with recalled product? Yes NO If yes, please explain:

Name: _____ Date: _____

Company (if applicable): _____

Address: _____

City/State/Zip _____

Phone: _____ Email: _____

Please complete this form and scan and email it to Omeza Customer Service at customerservice@omeza.com. If you have any questions or require further information, please contact our Customer Service at 888-886-6392, M-F 8:30am-5pm EST.