Meitheal Pharmaceuticals
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

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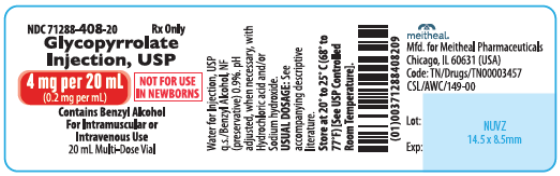
Customer Notification Recall Communication Letter

Urgent: Glycopyrrolate Injection, USP 4mg per 20mL RECALL

September 02, 2021

Dear Valued Customer:

This letter is to inform you that Meitheal Pharmaceuticals, Inc. ("Meitheal") is voluntarily recalling the following product:

Product	Lot Number	Expiration Date	NDC Number	Distribution Dates
Glycopyrrolate Injection, USP 4mg per 20mL 	G0010120	December 2021	71288-408-21 (unit of sale) 71288-408-20 (unit of use)	June 19, 2020 – November 16, 2020
Glycopyrrolate Injection, USP 4mg per 20mL 	G0080520	April 2022		November 16, 2020 – March 15, 2021
	G0090221	January 2023		June 01, 2021- August 16, 2021
	G0100221	January 2023		March 31, 2021 – May 24, 2021

This recall is being made with the knowledge of the Food and Drug Administration. Meitheal Pharmaceuticals, Inc. (Meitheal) announced the voluntary nationwide recall of four (4) lots of Glycopyrrolate Injection, USP 4mg per 20mL. This product was manufactured by Caplin Steriles Limited and distributed by Meitheal Pharmaceuticals, Inc. Meitheal has initiated this recall of Glycopyrrolate Injection, USP 4mg per 20mL because of an out of specification result observed for Benzaldehyde content during routine quality testing of stability samples at 18-month timepoint for Glycopyrrolate Injection, USP 4mg per 20mL Lot G0010120.

Benzaldehyde is an aromatic compound and can impact several organs like the brain, liver and kidney. Higher percentages of benzaldehyde concentration observed (up to 1%) is expected to result into negligible health risk. Although the occurrence of possible life-threatening situation, or exacerbation of preexisting patient conditions that could lead to life-threatening situations, could not be ruled out. To date, Meitheal has not received reports of any adverse events or identifiable safety concerns attributed to the lots listed in the table above.

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to the recall.

2. Immediately discontinue distribution of the above listed lots. Meitheal will issue a credit memo or check covering the quantity of your returned product.

3. Return product to:
   Integrated Commercialization Solutions, Inc. (ICS)
   6450 LaSalle Drive
   Lockbourne, OH 43137

   NOTE: Return shipment is free of charge. A Return Goods Authorization (RGA), a pre-printed, pre-paid return label will be provided to you for product return. Please submit the recall response form with the necessary information to MeithealPharmaReturns@icsconnect.com and a RGA and call tags will be issued. If you have further questions regarding the recall please contact Customer Service at 844-824-8426.

4. If you have further distributed this product, please identify your 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 response form.

5. Please complete and return the enclosed "Customer Recall Return Response Form" as soon as possible and email the completed form to MeithealPharmaReturns@icsconnect.com.

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

Your assistance is greatly appreciated. We apologize for any inconvenience this may cause you.

If you have any questions, please do not hesitate to call our Customer Service at 844-824-8426, weekdays 8:00AM to 6:00PM CST, to address any concerns that you may have.

Gail Giambi

Gail Giambi
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CUSTOMER RECALL RETURN RESPONSE FORM
GLYCOPYRROLATE INJECTION, USP 4mg per 20mL

Product	NDC Number	Lot Number	Expiration Dates	Distribution Dates	Quantity of cartons/packs to return*
Glycopyrrolate Injection, USP 4mg per 20mL	71288-408-21 (unit of sale) 71288-408-20 (unit of use)	G0010120	December 2021	June 19, 2020-August 16, 2021	
		G0080520	April 2022		
		G0090221	January 2023		
		G0100221	January 2023		

***Product is distributed as 10 vials per carton. Please make sure to outline the quantity to be returned in cartons/packs (unit of sale). If recording in vials, please ensure to specify this.**

Please check ALL appropriate boxes:

□ I have read and understand the recall instructions provided in the recall letter and that this recall is being carried out to the **user level**.

□ I have checked my inventory and have quarantined the product as outlined in the above table.

□ I would like to receive a pre-paid return label (Customer Service information below).

Return product to:
Integrated Commercialization Solutions, Inc. (ICS)
ATTN: Returns Department
6450 LaSalle Drive
Lockbourne, OH 43137

NOTE: Return shipment is free of charge. A Return Goods Authorization (RGA), a pre-printed, pre-paid return label will be provided to you for product return. Please submit the recall response form with the necessary information to MeithealPharmaReturns@icsconnect.com and a RGA and call tags will be issued. If you have further questions regarding the recall please contact Customer Service at 844-824-8426.

□ I have or will contact those further distributed to. This recall should be carried out to the **user level**.

Have there been any Adverse Events associated with the recalled product? □ Yes □ No
If yes, pleas explain:_____

Please check the appropriate box(es) to describe your business:
□ Wholesaler/distributor □ Pharmacy-retail □ Hospital/Medical Facility □ Other:

Please Complete Contact Information:	
Name:	
Date:	
Title:	
Phone #:	
Email:	
Facility Name:	
Address:	
City, State, Zip:	
Debit Memo #:	
Wholesaler:	
Wholesaler Account #:	

Note: Bolded items are required fields

PLEASE EMAIL TO MeithealPharmaReturns@icsconnect.com