



January 16, 2024

URGENT: DRUG RECALL

This is to inform you of a product recall involving:

Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed
Fosfomycin Tromethamine Granules For Oral Solution	22121458	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/20/2022	4,356
Fosfomycin Tromethamine Granules For Oral Solution	22121459	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/14/2022	4,536
Fosfomycin Tromethamine Granules For Oral Solution	22121460	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/14/2022	4,546
Fosfomycin Tromethamine Granules For Oral Solution	22121461	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/17/2022	4,452
Fosfomycin Tromethamine Granules For Oral Solution	22121462	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/17/2022	4,536
Fosfomycin Tromethamine Granules For Oral Solution	22121463	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	7/1/2022	4,536
Fosfomycin Tromethamine Granules For Oral Solution	22121464	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/24/2022	4,440
Fosfomycin Tromethamine Granules For Oral Solution	22121176	3 g /sachet	March 2024	7.5 g sachet pack	67877-749-57	5/27/2022	3,024
Fosfomycin Tromethamine Granules For Oral Solution	22121407	3 g /sachet	March 2024	7.5 g sachet pack	67877-749-57	5/27/2022	1,356



Fosfomycin Tromethamine Granules For Oral Solution	22121465	3 g /sachet	March 2024	7.5 g sachet pack	67877-749-57	7/1/2022	4,296
Fosfomycin Tromethamine Granules For Oral Solution	22121761	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	8/4/2022	4,392
Fosfomycin Tromethamine Granules For Oral Solution	22121762	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	8/18/2022	4,536
Fosfomycin Tromethamine Granules For Oral Solution	22121763	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	8/4/2022	4,524
Fosfomycin Tromethamine Granules For Oral Solution	22121764	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	8/2/2022	4,608
Fosfomycin Tromethamine Granules For Oral Solution	22121766	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	8/15/2022	4,608
Fosfomycin Tromethamine Granules For Oral Solution	22121968	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	9/15/2022	4,356
Fosfomycin Tromethamine Granules For Oral Solution	22121969	3 g /sachet	May 2024	7.5 g sachet pack	67877-749-57	9/15/2022	4,152

See enclosed product label for ease in identifying the product.

This recall has been initiated due to an out of specification result for the organic impurities test observed during stability testing of Fosfomycin Tromethamine Granules for Oral Solution. OOS were initially observed in seven batches (22121458, 22121459, 22121460, 22121461, 22121463, and 22121464). In efforts to assess the impact of the OOS, ten additional batches are being recalled.

This recall is being conducted with the knowledge of the Food and Drug Administration. This recall should be conducted to the WHOLESALE level.

Please perform the following activities:

- a. Immediately examine your inventory and quarantine product subject to recall for the lot number specified in the table above.



The completed Recall Response Form can be submitted by any of the below methods:

Fax: 817-868-5362

E-mail: rxrecalls@inmar.com

Your assistance is appreciated and necessary in this voluntary recall. If you have any question related to customer service, please contact product inquiries—available 24 hours a day—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 817-810-7153—available 9:00 AM to 5:00 PM ET Monday through Friday.

Sincerely,

HSchiff@ascend
aboratories.com

Digitally signed by
HSchiff@ascendlaboratories.com
Date: 2024.01.16 12:24:11 -05'00'

Hindy Schiff

Vice President, Regulatory/Compliance

RECALL STOCK RESPONSE FORM

Recall-Fosfomycin Tromethamine for Oral Solution

Lots: 22121176, 22121407, 22121458, 22121459, 22121460, 22121461, 22121462, 22121463, 22121464, 22121465, 22121761, 22121763, 22121764, 22121766, 22121968, 22121969

Customer Name: _____ DEA #: _____

Please note that DEA # is required. If it is not provided, the processing of your form will be delayed.

Address: _____

City: _____ State: _____ Zip Code: _____

Contact Name (please print): _____ Telephone #: _____

Contact Signature: _____ Date: _____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____ Wholesaler DEA#: _____

Wholesaler City: _____ Wholesaler State: _____ Wholesaler Zip: _____

Please check and fill out each section accordingly.

- I have read and understand the recall instructions provided in the Recall Letter.
- I have checked my stock for the quarantined inventory indicated in the table below.

Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity on Hand to Return
Fosfomycin Tromethamine Granules For Oral Solution	22121458	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/20/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121459	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/14/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121460	3 g /sachet	April 2024	7.5 g sachet pack	67877-749-57	6/14/2022	

Fosfomycin Tromethamine Granules For Oral Solution	22121461	3 g /sachet	April 2024	7.5 g sachet pack	67877- 749-57	6/17/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121462	3 g /sachet	April 2024	7.5 g sachet pack	67877- 749-57	6/17/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121463	3 g /sachet	April 2024	7.5 g sachet pack	67877- 749-57	7/1/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121464	3 g /sachet	April 2024	7.5 g sachet pack	67877- 749-57	6/24/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121176	3 g /sachet	March 2024	7.5 g sachet pack	67877- 749-57	5/27/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121407	3 g /sachet	March 2024	7.5 g sachet pack	67877- 749-57	5/27/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121465	3 g /sachet	March 2024	7.5 g sachet pack	67877- 749-57	7/1/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121761	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	8/4/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121762	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	8/18/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121763	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	8/4/2022	

Fosfomycin Tromethamine Granules For Oral Solution	22121764	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	8/2/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121766	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	8/15/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121968	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	9/15/2022	
Fosfomycin Tromethamine Granules For Oral Solution	22121969	3 g /sachet	May 2024	7.5 g sachet pack	67877- 749-57	9/15/2022	

Indicate disposition of recall product:

Returned/Held for Return (Yes / No)

- Quantity: _____
- Date: _____
- Method: _____

OR

No recall product on hand (Yes / No)

I have identified and notified my customers that were shipped/received or may have been shipped this product by:

- Date: _____
- Method of Notification: _____

Were there any adverse events associated with the recalled product?

- Yes
- No

If yes, please explain: _____

If you have any questions regarding this form or product return, please contact Inmar at 1-877-810-7153.
Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.

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

After receipt of this response form, a return kit will be provided for affected product return to:

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