



July 18, 2023

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	22121970	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	4392 units
Fosfomycin Tromethamine Granules for Oral Solution	22122158	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	9024 units
Fosfomycin Tromethamine Granules for Oral Solution	22121971	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	4296 units
Fosfomycin Tromethamine Granules for Oral Solution	22122189	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	9000 units
Fosfomycin Tromethamine Granules for Oral Solution	22122190	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	9144 units
Fosfomycin Tromethamine Granules for Oral Solution	22122277	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	4320 units
Fosfomycin Tromethamine Granules for Oral Solution	22122278	3g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	4104 units

Fosfomycin Tromethamine Granules for Oral Solution	22122521	3g Sachet	July 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	November 2022	8856 units
Fosfomycin Tromethamine Granules for Oral Solution	22122522	3g Sachet	July 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	9396 units
Fosfomycin Tromethamine Granules for Oral Solution	22122523	3g Sachet	July 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	8928 units
Fosfomycin Tromethamine Granules for Oral Solution	22123328	3g Sachet	September 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	January 2023	9288 units
Fosfomycin Tromethamine Granules for Oral Solution	22123329	3g Sachet	September 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	January 2023	9408 units
Fosfomycin Tromethamine Granules for Oral Solution	22123330	3g Sachet	September 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	January 2023	9360 units

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 at 6 months, RT stability conditions. OOS were observed in two batches of Fosfomycin Tromethamine Granules for Oral Solution 3 g/sachet, batch numbers 22121970 and 22122158.

As a part of impact assessment, samples of thirteen batches (listed in table) manufactured after batch number 22121970 were analyzed for organic impurities, assay, water content and reconstitution time tests. All the results were found to meet the finished product specification criteria. As a precautionary measure this recall is being initiated.

Under the knowledge of the Food and Drug Administration, this recall should be conducted to the wholesale level (Class III).

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.

- b. Promptly complete the attached recall stock response form even if you have no product to return.

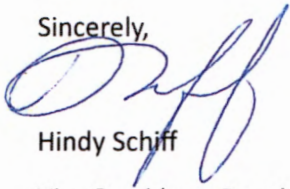
The completed Recall Response Form can be submitted by any of the below methods:

Fax: 817-868-5362

E-mail: rxrecalls@inmar.com

Your assistance is appreciated and necessary in this voluntary recall. If you have any questions 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 877-672-9474.

Sincerely,



Hindy Schiff

Vice President, Regulatory Affairs/Compliance

RECALL STOCK RESPONSE FORM

Recall – Fosfomycin Tromethamine Granules for Oral Solution, 3 g

Level III – Wholesale

Please fill out this form completely. By doing so, this will acknowledge that you have read and understood the recall instructions and have taken appropriate action.

Customer Name: _____ DEA #: _____

*Please note 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 Code: _____

I have checked my stock and:

_____ Do not have any of the recalled items.

OR

I have quarantined and listed in the box below the quantity of recall units, and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar will issue a return authorization label (s). Please indicate the number of required box labels: _____

I confirm that all locations that have received impacted product have been notified to the wholesale level.

Initial _____ Date: _____

Please see the table below and indicate the amount of product you have on hand in the appropriate column/row of the table.

Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity on Hand
Fosfomycin Tromethamine Granules for Oral Solution	22121970	3 g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	4392 Units
Fosfomycin Tromethamine Granules for Oral Solution	22122158	3 g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	9024 Units
Fosfomycin Tromethamine Granules for Oral Solution	22121971	3 g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	4296 Units
Fosfomycin Tromethamine Granules for Oral Solution	22122189	3 g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	9000 Units
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Fosfomycin Tromethamine Granules for Oral Solution	22122277	3 g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	4320 Units
Fosfomycin Tromethamine Granules for Oral Solution	22122278	3 g Sachet	June 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	September 2022	4104 Units
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Fosfomycin Tromethamine Granules for Oral Solution	22122522	3 g Sachet	July 202	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	October 2022	9396 Units
Fosfomycin Tromethamine Granules for Oral Solution	22123328	3 g Sachet	September 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	January 2023	9288 Units
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Fosfomycin Tromethamine Granules for Oral Solution	22123330	3 g Sachet	September 2024	Single Dose Sachet (equivalent to 3 g of Fosfomycin)	67877-749-57	January 2023	9360 Units

If you have any questions regarding this form or product return, please contact Inmar at 877-672-9474, Office Hours: 9:00 AM to 5:00PM CT Monday through Friday.

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

Batch No.

Back side of Sachet

Front side of Sachet

22121970

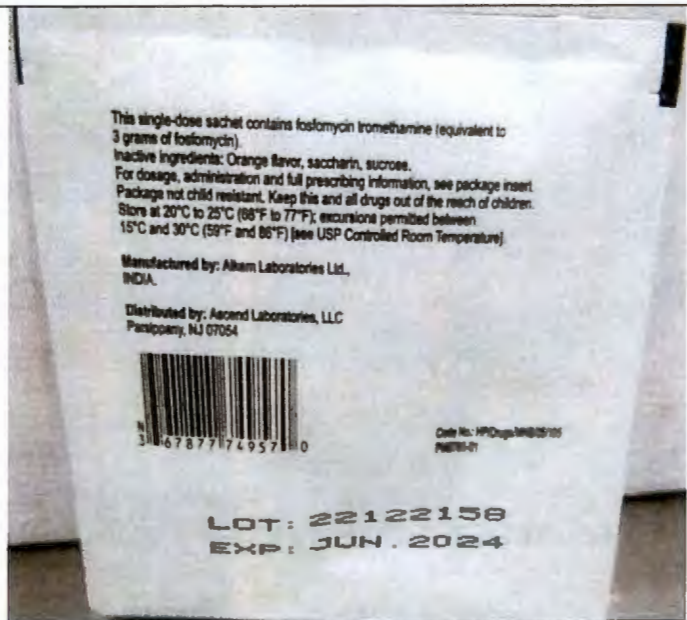


22121971

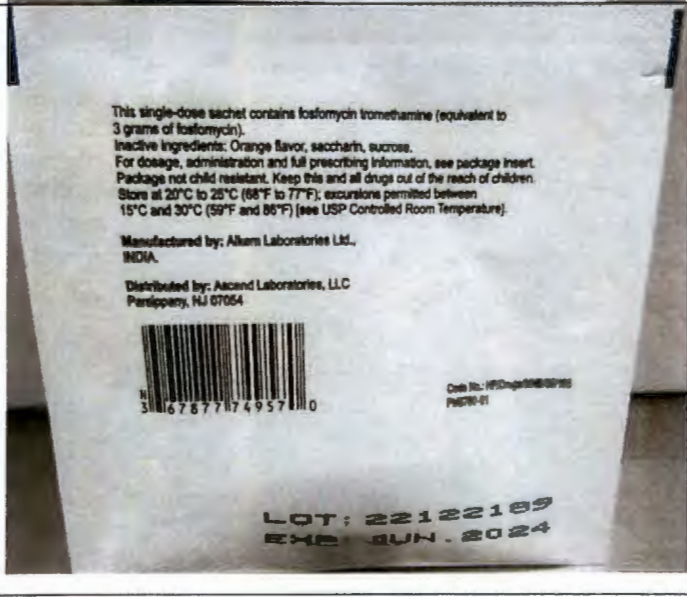


Batch No.	Back side of Sachet	Front side of Sachet
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22122158



22122189

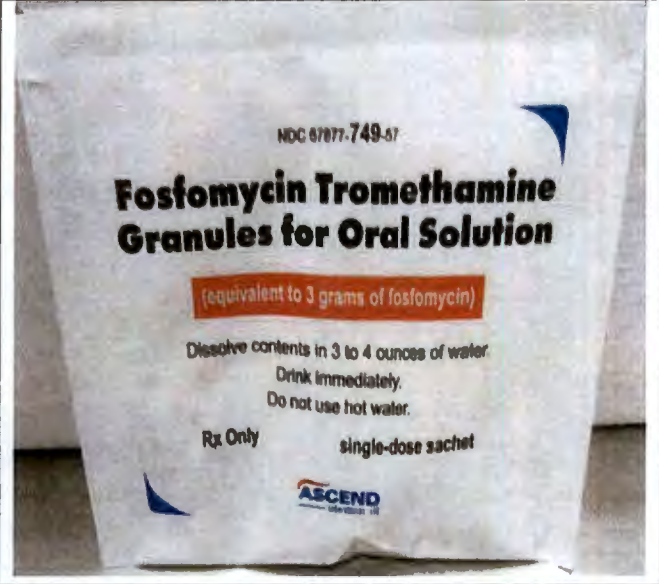
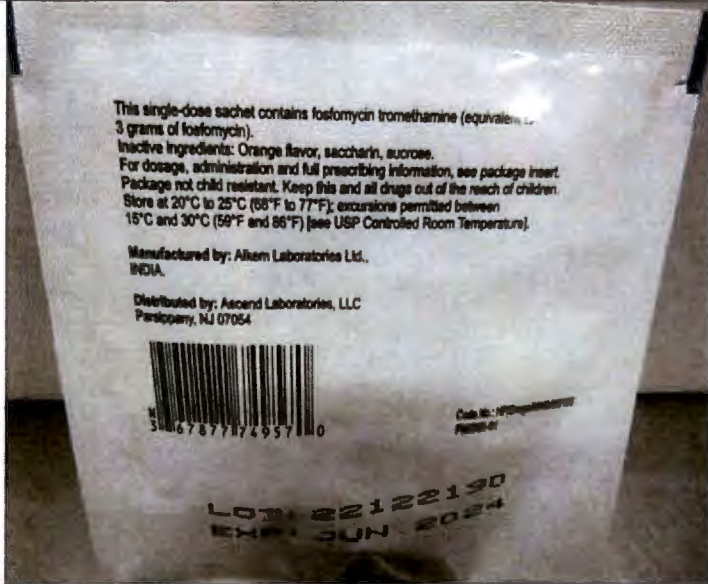


Batch No.

Back side of Sachet

Front side of Sachet



22122190





22122277



Batch No.	Back side of Sachet	Front side of Sachet
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22122278	<p>This single-dose sachet contains fosfomycin tromethamine (equivalent to 3 grams of fosfomycin). Inactive ingredients: Orange flavor, saccharin, sucrose. For dosage, administration and full prescribing information, see package insert. Package not child resistant. Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].</p> <p>Manufactured by: Alkem Laboratories Ltd., INDIA.</p> <p>Distributed by: Ascend Laboratories, LLC Parippany, NJ 07054</p>  <p>N 3 67877 174957 1 0</p> <p>Code No.: HPIDrugsAMB/05/155 PM780-01</p> <p>LOT: 22122278 EXP: MAY . 2024</p>	<p>NDC 67877-749-57</p> <h2>Fosfomycin Tromethamine Granules for Oral Solution</h2> <p>(equivalent to 3 grams of fosfomycin)</p> <p>Dissolve contents in 3 to 4 ounces of water. Drink immediately. Do not use hot water.</p> <p>Rx Only single-dose sachet</p> 
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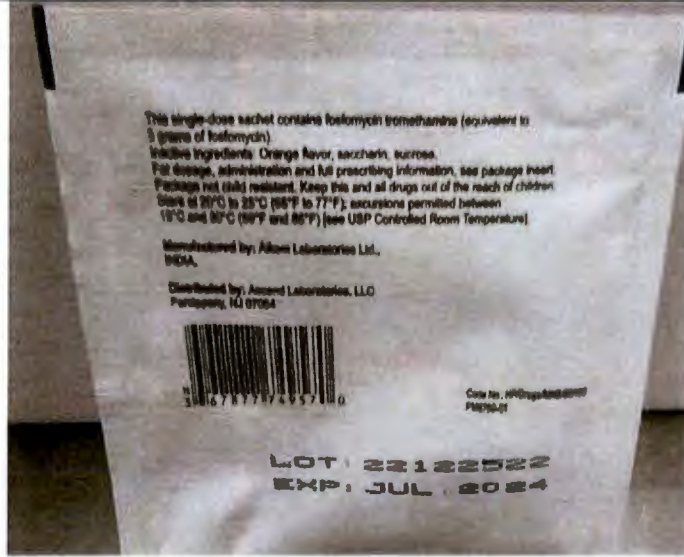
22122521	<p>This single-dose sachet contains fosfomycin tromethamine (equivalent to 3 grams of fosfomycin). Inactive ingredients: Orange flavor, saccharin, sucrose. For dosage, administration and full prescribing information, see package insert. Package not child resistant. Keep this and all drugs out of the reach of children. Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].</p> <p>Manufactured by: Alkem Laboratories Ltd., INDIA.</p> <p>Distributed by: Ascend Laboratories, LLC Parippany, NJ 07054</p>  <p>N 3 67877 174957 1 0</p> <p>Code No.: HPIDrugsAMB/05/155 PM780-01</p> <p>LOT: 22122521 EXP: JUL . 2024</p>	<p>NDC 67877-749-57</p> <h2>Fosfomycin Tromethamine Granules for Oral Solution</h2> <p>(equivalent to 3 grams of fosfomycin)</p> <p>Dissolve contents in 3 to 4 ounces of water. Drink immediately. Do not use hot water.</p> <p>Rx Only single-dose sachet</p> 
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Batch No.

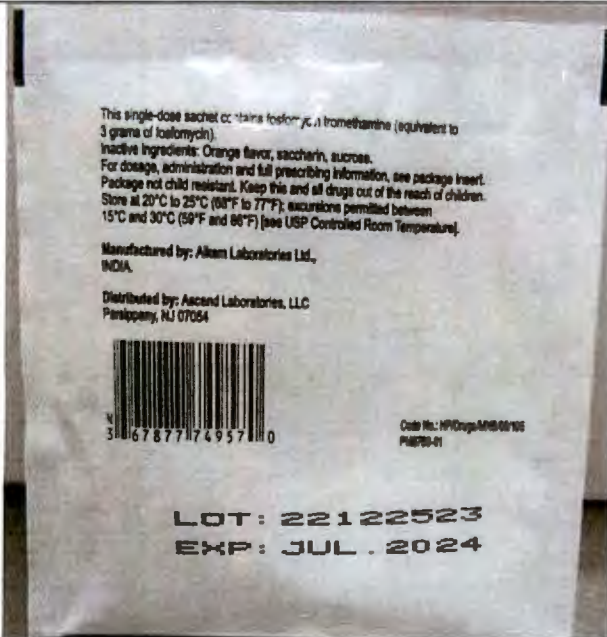
Back side of Sachet

Front side of Sachet

22122522



22122523

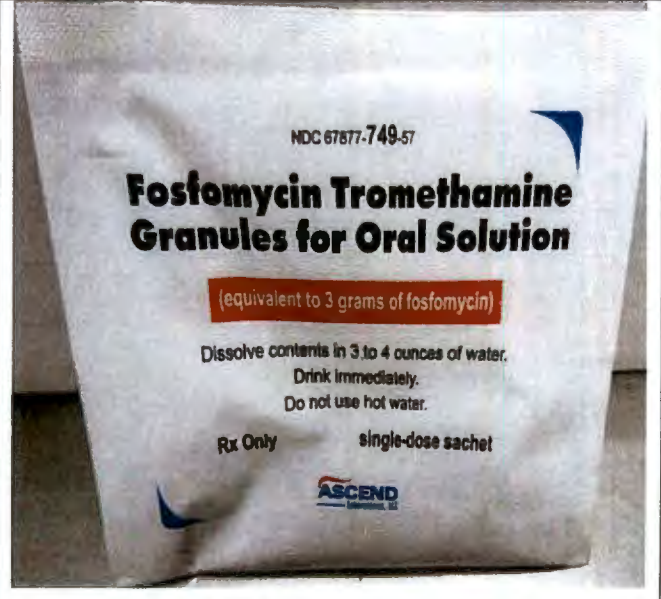
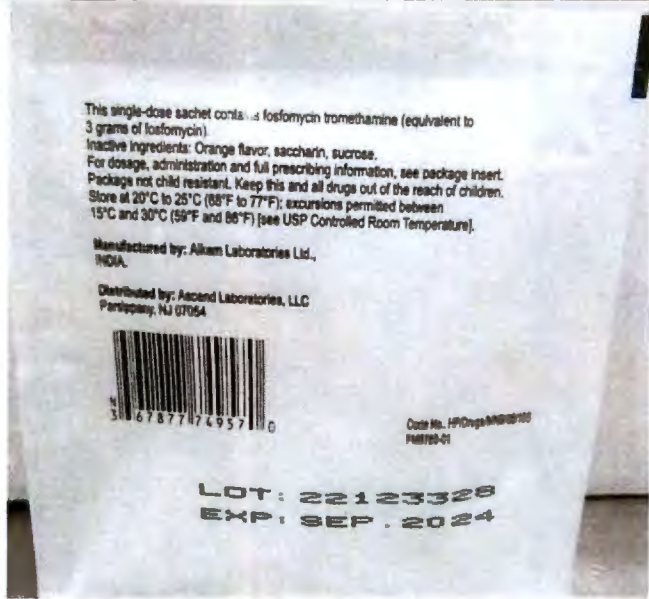


Batch No.

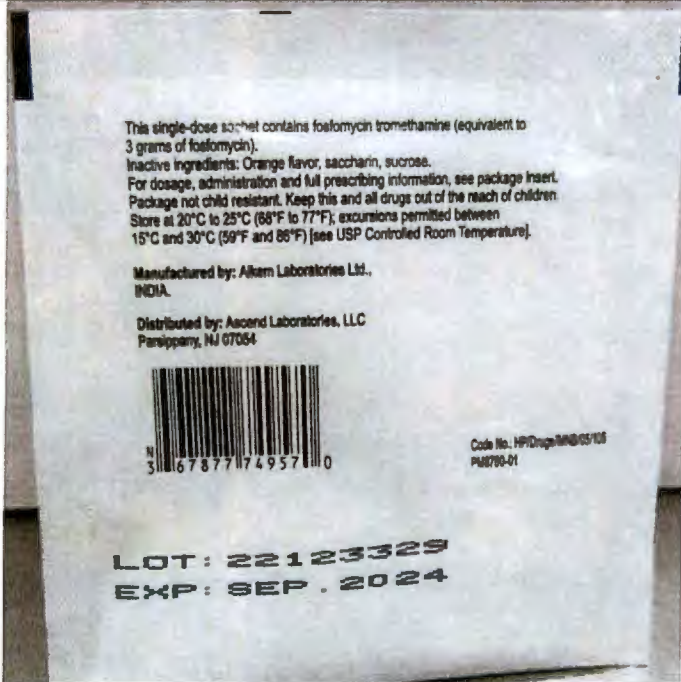
Back side of Sachet

Front side of Sachet

22123328



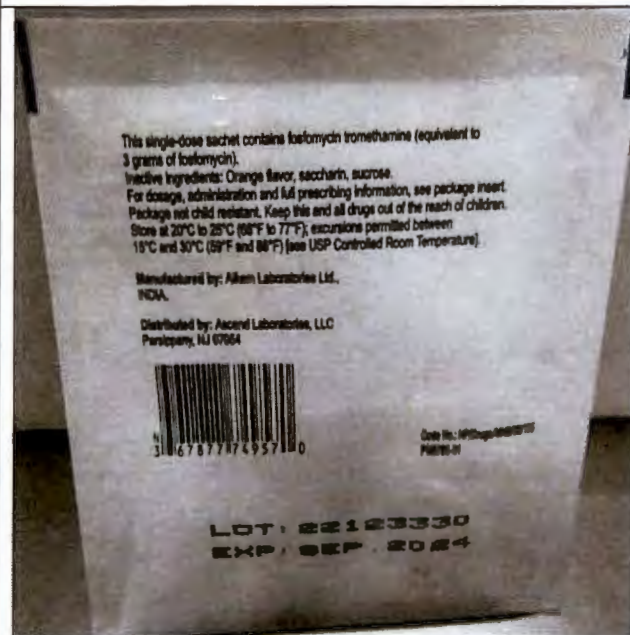
22123329



**Batch
No.**

22123330

Back side of Sachet



Front side of Sachet

