

URGENT: DRUG RECALL – CONSUMER LEVEL

August 2, 2022
Event # 7210

PRODUCT	Product	NDC Number	Lot Number	Expiry Date
	Magnesium Citrate Saline Laxative Lemon Flavor, 10 FL OZ (296 mL)	0904-6787-44	See Attachment 1	
Distributed by: Major Pharmaceuticals		Recalled by: Vi-Jon, Inc. Smyrna, TN 37167		
REASON	<p>Major Pharmaceuticals has been notified by Vi-Jon, Inc. that they are voluntarily recalling to the CONSUMER LEVEL, the product / lots indicated in the above table. "This recall is the result of testing showing that certain lots of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor exceed the limit for Aerobic Plate Count & Yeast and Mold (identified as Gluconacetobacter liquefaciens). While all product passed prior to release for distribution recent testing of retain samples has shown that certain lots exceed the limit for Total Yeast and Mold. The organism recovered in Total Yeast and Mold testing was Gluconacetobacter liquefaciens. Based on our assessment, Vi-Jon has concluded immunocompromised patients, who consume this product, may be at increased risk for invasive infections caused Gluconacetobacter liquefaciens that could lead to serious, life threatening adverse health consequences."</p>			
ACTIONS TO BE TAKEN	<ol style="list-style-type: none"> 1. Stop distributing and quarantine the affected lots. 2. Please carry out a physical count and record this data on the Business Reply Form / Packing Slip which is included with this letter. 3. Fax the Business Reply Form / Attachment 1 even if you do not have the recalled product to 1-888-879-4064 or email to MajorRugby7210@sedgwick.com 4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to: <div style="margin-left: 40px;"> Sedgwick, Inc. 2670 Executive Dr., Suite A Indianapolis, IN 46241 Attn: Event # 7210 </div> 5. If you have further distributed the product, please notify your customers down to the CONSUMER LEVEL immediately and have them return the product back to you. 			
OTHER INFORMATION	<p>This recall is being carried out to the CONSUMER LEVEL and is only for the specific product / lots listed above. No other lots, packages, or formulations are being recalled.</p> <p>These lots were shipped from our Indianapolis warehouse between 09/16/2020 and 07/18/2022.</p> <p>For questions regarding returns, please contact Sedgwick at 1-888-943-2387. For medical-related questions, please contact your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.</p> <p>To ensure proper credit, please return recalled merchandise before <u>January 31, 2023</u>. Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.</p> <p>This recall is being made with the knowledge of the FDA. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.</p>			

BUSINESS REPLY FORM / PACKING SLIP

Please make a copy of this form to include with your product return shipment.

August 2, 2022**Event # 7210****Product:** Magnesium Citrate Saline Laxative Lemon Flavor, 10 FL OZ (296 mL)**Affected NDC Number:** 0904-6787-44**Affected Lot Numbers:** Please see Attachment 1

Your timely response to the recall notification is requested. Please fill out and fax this reply form within five (5) days, even if you do not have the recalled product. Thank you.

Please complete and fax or email to: **Sedgwick at: Fax: 1-888-879-4064**
Email: MajorRugby7210@sedgwick.com

Wholesaler Name: _____ Wholesaler Acct #: _____

Debit Memo Number: _____

Signature: _____ Title: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Please check one:

- We do not have any of the recalled products on hand.
- We have quarantined the following recalled product(s) and will return them as requested:

(Please include a copy of Attachment 1 with your response)

Affected Product:

Product	NDC Number	Lot Number	Expiry Date
Magnesium Citrate Saline Laxative Lemon Flavor, 10 FL OZ (296 mL)	0904-6787-44	See Attachment 1	

Distributed by: Major Pharmaceuticals**Recalled by: Vi-Jon, Inc.
Smyrna, TN 37167**

Attachment 1

August 2, 2022

Event # 7210

Product	NDC Number
Magnesium Citrate Saline Laxative Lemon Flavor, 10 FL OZ (296 mL)	0904-6787-44

We have quarantined the following recalled product(s) and will return them as requested:
 (Please include a copy of Attachment 1 with your response)

Lot Number	Expiry Date	Quantity to be Returned	Lot Number	Expiry Date	Quantity to be Returned
0498815	08/2022		0537781	06/2023	
0498819	08/2022		0537782	06/2023	
0501884	09/2022		0537783	06/2023	
0501885	09/2022		0539834	08/2023	
0501886	09/2022		0539835	07/2023	
0501887	09/2022		0539835R2	07/2023	
0501888	09/2022		0539836	08/2023	
0505247	10/2022		0542935R1	09/2023	
0505248	10/2022		0542935R2	09/2023	
0505249	10/2022		0542936	09/2023	
0508944	11/2022		0542936R1	09/2023	
0508953	11/2022		0542937	09/2023	
0508955	11/2022		0542937R1	09/2023	
0508956	11/2022		0542938	09/2023	
0508957	11/2022		0542938R1	09/2023	
0508959	11/2022		0542939	09/2023	
0511721	12/2022		0542939R1	09/2023	
0511723	12/2022		0542940	09/2023	
0518460	12/2022		0542940R2	09/2023	
0518461	12/2022		0551895	10/2023	
0518462	12/2022		0551968	11/2023	
0518463	01/2023		0551969	11/2023	
0518464	01/2023		0551970	11/2023	
0518465	12/2022		0556094	12/2023	
0518467	01/2023		0556817	12/2023	
0518468	01/2023		0558192	01/2024	
0528485	04/2023		0562244	02/2024	
0528486	03/2023		0562306	03/2024	
0528488	04/2023		0562309	03/2024	
0530048	04/2023		0563518	03/2024	
0533216	05/2023		0563520	03/2024	
0533217	05/2023		0563595	04/2024	
0534876	06/2023		0564023	03/2024	
0537774	06/2023		0567126	05/2024	
0537775	06/2023		0568829	04/2024	
0537776	06/2023		0569326	05/2024	
0537777	06/2023		0570583	06/2024	
0537779	06/2023		0570584	06/2024	
0537780	06/2023		0572458	06/2024	

Please complete and fax or email to:

Sedgwick at: Fax: 1- 888-879-4064 or Email: MajorRugby7210@sedgwick.com

Wholesaler Name: _____ Wholesaler Acct #: _____

Debit Memo Number: _____

Signature: _____ Title: _____

Address: _____

City: _____ State: _____ Zip Code: _____