

FDA Drug Recall

Vi-Jon, LLC Issues Voluntary Nationwide Recall of CVS Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor Due to Microbial Contamination

6/22/2022 – June 21, 2022 - Smyrna, TN, Vi-Jon, LLC is voluntarily recalling 1 (one) lot of CVS Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor, 10 FL OZ (296 mL) to the consumer level. Testing identified the affected lot of the product to contain the bacteria *Gluconacetobacter liquefaciens*.

Risk Statement: Immunocompromised patients, who consume this product, may be at increased risk for invasive infections caused by *Gluconacetobacter liquefaciens* that could lead to serious, life threatening adverse health consequences. To date, Vi-Jon, LLC has not received any complaints related to this recall.

The product is used for relief of occasional constipation (irregularity) and generally produces bowel movement in 1/2 to 6 hours. The product is packaged in a 10 oz clear round plastic bottle. The affected CVS Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor lot includes the following batch number: 0556808 and expiration date: 12/2023 on the shoulder of the bottle. This lot of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor was sent to a 3rd Party Outside Lab for testing per CVS request as a first production sample for CVS. This lot of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor was distributed Nationwide at CVS drug store locations.

Vi-Jon, LLC has already notified CVS by phone and email and is arranging for return of all recalled product.

Consumers that have this recalled product should stop using and return any remaining product to the place of purchase.

Consumers with questions regarding this recall can contact Vi-Jon, LLC by e-mail Recalls@Vijon.com Monday-Friday, from 7:30 am to 4:30 pm Central Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Vi-Jon, LLC
Recalls@Vijon.com

Media:

Mr. Joseph Meehan, Chief Sales and Marketing Officer
 847-980-6239

Product Photos



DO NOT USE IF TAMPER EVIDENT TWIST-OFF CAP IS MISSING, BROKEN OR SEPARATED FROM NECKRING

<p>Drug Facts</p> <p>Active ingredient (in each fl oz) Purpose Magnesium citrate 1.745 g Saline laxative</p> <p>Uses ■ for relief of occasional constipation (irregularity). ■ Generally produces bowel movement in 1/2 to 6 hours</p> <p>Warnings Ask a doctor before use if you have: ■ kidney disease ■ a magnesium restricted diet ■ abdominal pain, nausea, or vomiting ■ noticed a sudden change in bowel habits that persists over a period of 2 weeks ■ already used a laxative for a period longer than 1 week Ask a doctor or pharmacist before use if you are: ■ taking any other drug. ■ Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work. Stop use and ask a doctor if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help</p>		<p>Drug Facts (continued)</p> <p>or contact a Poison Control Center right away. Store at temperatures between 40° and 80° F (4° and 30° C)</p> <p>Directions ■ shake well before using ■ drink a full glass (8 ounces) of liquid with each dose ■ may be taken as a single daily dose or in divided doses</p> <table border="1"> <tr> <td>adults and children 12 years of age and over</td> <td>6.5 to 10 fl oz maximum 10 fl oz in 24 hours</td> </tr> <tr> <td>children 6 to under 12 years of age</td> <td>3 to 7 fl oz maximum 7 fl oz in 24 hours</td> </tr> <tr> <td>children 2 to under 6 years of age</td> <td>2 to 3 fl oz maximum 3 fl oz in 24 hours</td> </tr> <tr> <td>children under 2 years of age</td> <td>ask a doctor</td> </tr> </table> <p>Other information ■ each fl oz contains: magnesium 290 mg ■ each fl oz contains: sodium 1 mg</p> <p>Inactive ingredients benzoic acid, citric acid, disodium EDTA, flavor, sucralose, water</p>		adults and children 12 years of age and over	6.5 to 10 fl oz maximum 10 fl oz in 24 hours	children 6 to under 12 years of age	3 to 7 fl oz maximum 7 fl oz in 24 hours	children 2 to under 6 years of age	2 to 3 fl oz maximum 3 fl oz in 24 hours	children under 2 years of age	ask a doctor
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#209452 L001766880

Product Insert
Milk of Magnesia, USP
 NDC 0504-0046-73
 10 x 30 mL Unit Dose Caps

Drug Facts

Active ingredient (in each 30 mL cup)	Purpose
Magnesium Hydroxide USP 2400 mg	Stool softener

Uses ■ relieves occasional constipation (irregularity)
 ■ prevents postoperative bowel movement in 14 to 6 hours

Warnings

Ask a doctor before use if you have

- kidney disease ■ a magnesium-related diet
- stomach pain, bloating, or vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product 1 to 2 hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if ■ you have rectal bleeding or no bowel movement after using this product. These could be signs of a serious condition.
 ■ you need to use a laxative for more than 1 week

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- do not exceed the maximum recommended daily dose in a 24-hour period
- shake well before use
- dose may be taken once a day preferably at bedtime, or as directed by a doctor
- drink a full glass (8 oz) of liquid with each dose

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 60 mL in 24 hrs
children under 12 years	ask a doctor

Other information

- each 30 mL contains: calcium 40 mg, sodium 106 mg, and magnesium 1068 mg
- store at 20-25°C (68-77°F) ■ avoid heat, excessive moisture
- avoid use if lid seal is open or damaged ■ sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients: citric acid, glycerin, hydroxypropyl cellulose, methylcellulose, croscarmellose sodium, sodium citrate, xanthan gum, water

Questions or comments?
 Call 1-800-615-0473

MAJOR
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 17177 N Laurel Park Dr., Suite 233
 Livonia, MI 48150

16-154
 C05030 R3
 Rev. 03/19

Product Insert
Milk of Magnesia Concentrate
 NDC 5961-6940-72
 10 x 10 mL Unit Dose Caps

Drug Facts	
Active ingredient (in each 10 mL cap): Magnesium Hydroxide USP 2400 mg	Purpose: Saline laxative
Uses ■ relieve occasional constipation (irregularity) ■ promote peristalsis, bowel movement in 1/2 to 6 hours	
Warnings Ask a doctor before use if you have ■ kidney disease ■ a magnesium-restricted diet ■ stomach pain, bloating, or vomiting ■ a sudden change in bowel habits that lasts more than 2 weeks Ask a doctor or pharmacist before use if you are taking any other drug. Laxatives may affect how other drugs work. Stop use and ask a doctor if ■ you have rectal bleeding or no bowel movements after using this product. These could be signs of a serious condition. ■ you need to use a laxative for more than 1 week. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
Directions ■ Do not exceed the maximum recommended daily dose in a 24-hour period. ■ Shake well before use. ■ Dose may be taken once a day preferably at bedtime, in divided doses, or as directed by a doctor. ■ Shake & stir (S&S) thoroughly with each dose.	
Age (yr)	Dose (mL)
adults and children 12 years and over	10 mL, not more than 30 mL in 24 hours
children under 12 years	ask a doctor
Other information ■ each 10 mL contains calcium 40 mg, sodium 60 mg, and magnesium 1800 mg ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture ■ do not use if lid seal is open or damaged ■ sugar free, dye free, alcohol free ■ see bottom of cap for lot number and expiration date	
Inactive ingredients zinc acid, glycerin, microcrystalline cellulose, methylcellulose, polyethylene glycol, polyethylene glycol, sodium citrate, sorbitol, xanthan gum, and water	
Questions or comments? Call 1-800-615-2473	

Re-order No. 701033

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M-184
C850508
Rev. 02/18

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/vi-jon-llc-issues-voluntary-nationwide-recall-cvs-magnesium-citrate-saline-laxative-oral-solution?utm_medium=email&utm_source=govdelivery