

# **Important Drug Recall Notice**

### TO ALL PARTICIPATING PHARMACIES

#### Circular Letter MC22-070-CG July 29, 2022

FDA announced that, Smyrna, TN, Vi-Jon, LLC is expanding its voluntary recall to include all lots of all flavors of Magnesium Citrate Saline Laxative Oral Solution within expiry to the consumer level. This expansion includes all lots of Cherry Flavor and Grape Flavor of Magnesium Citrate Saline Laxative Oral Solution, 10 FL OZ (296 mL) within expiry. On July 14, 2022, Vi-Jon, LLC recalled all lots of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor, 10 FL OZ (296 mL) within expiry. The recall was initiated after Vi-Jon, LLCs third party microbial testing identified the presence of *Gluconacetobacter liquefaciens*.

### RECOMMENDATIONS

- 1. Vi-Jon, LLC is notifying its customers by phone and email and is arranging for return or destruction of all recalled product. Consumers that have this recalled product should stop using and return any remaining product to the place of purchase.
- 2. Consumers with questions regarding this recall can contact Vi-Jon, LLC by e-mail (Recalls@Vijon.com) Monday to 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. <u>www.vijon.com</u>
- 3. Review your inventory to identify existence of recalled products.
- 4. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

#### **MC-Rx Pharmacy Services Department**

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#### Vi-Jon, LLC Expands Voluntary Nationwide Recall of All Flavors and Lots within Expiry of Magnesium Citrate Saline Laxative Oral Solution Due to Microbial Contamination

#### Summary:

FDA Publish Date:July 26, 2022Product Type:Drugs	Company Announcement Date:	July 25, 2022
Product Type: Drugs	FDA Publish Date:	July 26, 2022
	Product Type:	Drugs
<b>Reason for Announcement:</b> Potential Gluconacetobacter liquefaciens contamination	<b>Reason for Announcement:</b>	Potential Gluconacetobacter liquefaciens contamination
Company Name: Vi-Jon, LLC	Company Name:	Vi-Jon, LLC
Brand Name: Multiple Brands	Brand Name:	Multiple Brands
Product Description: Magnesium Citrate Saline Laxative Oral Solution	Product Description:	Magnesium Citrate Saline Laxative Oral Solution

#### **Company Announcement**

**FOR IMMEDIATE RELEASE** – **July 25, 2022** – Smyrna, TN, Vi-Jon, LLC is expanding its voluntary recall to include all lots of all flavors of Magnesium Citrate Saline Laxative Oral Solution within expiry to the consumer level. This expansion includes all lots of Cherry Flavor and Grape Flavor of Magnesium Citrate Saline Laxative Oral Solution, 10 FL OZ (296 mL) within expiry. On July 14, 2022, Vi-Jon, LLC recalled all lots of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor, 10 FL OZ (296 mL) within expiry. The recall was initiated after Vi-Jon, LLCs third party microbial testing identified the presence of *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 is aware of **3 (three)** reports of serious adverse reactions potentially related to this recall. Vi-Jon, LLC is in the process of investigating these reports.

The product is used for relief of occasional constipation (irregularity) and generally produces bowel movement in  $\frac{1}{2}$  to 6 hours. The product is packaged in a 10 oz clear round plastic bottle.

## In addition to the lemon flavor, the recall now includes the Cherry flavor and Grape flavor noted in the table below.

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U.S. FOOD & DRUG

Affected Brand UPC # NDC # BEST CHOICE 10OZ LEMON MAG CITRATE 63941-533-38 070038200499 BEST CHOICE 100Z CHERRY CITRATE 63941-516-38 070038587903 BEST CHOICE 100Z GRAPE CITRATE 63941-162-38 070038662204 CARE ONE 100Z LEMON MAG CIT 72476-001-38 341520313226 CARE ONE 100Z CHERRY CIT 72476-002-38 341520000553 CARIBA 100Z LEMON MAG CITRATE 67860-166-38 646702057012 CRUZ BLANC 100Z LEMON MAG CIT N/A 308697403082 63868-929-38 CVS 10OZ LEMON MAG CIT 050428335178 CVS 10OZ LEMON MAG CIT 69842-983-38 050428305942 CVS 10OZ CHERRY CITRATE 69842-647-38 050428297339 CVS 10OZ CHERRY CITRATE 69842-647-38 00050428285152 CVS 10OZ CLR GRAPE CITRATE 69842-763-38 050428307458 CVS 10OZ CLR GRAPE CITRATE 69842-763-38 00050428325032 DISCOUNT DRUG MART 100Z LEMON MAG CITRATE 53943-166-38 093351028205 EQUALINE 100Z LEMON MAG CIT 41163-709-38 041163500679 41163-769-38 EQUALINE 10OZ CHERRY CITRATE 041163500686 EQUATE 100Z LEMON MAG CIT SRP 49035-506-38 681131287142 EQUATE 10OZ CHERRY CIT SRP 49035-593-38 681131287166 EQUATE 100Z GRAPE MAG CIT SRP 49035-592-38 681131287159 EXCHANGE SELECT 100Z LEMON MAG CIT 55301-166-38 614299404205 FAMILY WELLNESS 100Z LEMON CITRATE 55319-666-38 032251580826 FAM WELLNS 10OZ CHERRY CITRATE 55319-164-38 032251577888 GOOD SENSE 100Z LEMON MAG CIT 50804-166-38 846036007374 GOOD SENSE 100Z CHERRY CITRATE 50804-164-38 846036007398 HARRIS TEETER 100Z LEMON MAG CITRATE 72036-002-38 072036726124 HEB 100Z LEMON MAG CITRATE 37808-769-38 041220510863

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U.S. FOOD & DRUG FDA

Affected Brand	NDC #	UPC #
HEB 100Z CHERRY CITRATE	37808-673-38	00041220510870
HEB 100Z GRAPE MAG CITRATE	37808-695-38	00041220510887
HEALTH MART 100Z LEMON MAG CIT	62011-0380-1	052569142158
HEALTH MART 100Z CHERRY CIT	62011-0381-1	052569142165
KROGER 100Z LEMON MAG CITRATE	30142-899-38	041260001826
KROGER 100Z GRAPE CITRATE	30142-806-38	041260008719
LEADER 100Z LEMON MAG CIT	70000-0424-1	096295135541
LEADER 100Z CHERRY CIT	70000-0575-1	096295141061
LEADER 100Z GRAPE MAG CIT	70000-0576-1	096295141054
MAJOR 100Z LEMON MAG CITRATE	0904-6787-44	309046787440
MEIJER 100Z LEMON MAG CIT	41250-708-38	713733459457
MEIJER 100Z CHERRY CITRATE	41250-769-38	713733459440
PREMIER VALUE 100Z LOW SOD LEM CIT	68016-696-38	840986035302
PREMIER VALUE 100Z CHERRY CIT	68016-701-38	840986035296
PUBLIX 100Z LEMON MAG CIT	56062-266-38	041415506732
PUBLIX 10OZ CHERRY CITRATE	56062-264-38	041415505735
QUALITY CHOICE 100Z LEMON MAG CIT	63868-929-38	635515901254
QUALITY CHOICE 100Z CHERRY CITRATE	63868-018-38	635515901117
REXALL 100Z LEMON MAG CITRATE	55910-183-38	072785134188
REXALL 10OZ CHERRY CIT	55910-961-38	072785134164
REXALL 10OZ GRAPE MAG CIT	55910-615-38	072785134171
RITE AID 100Z LEMON CITRATE	11822-4330-2	011822433006
RITE AID 100Z CHERRY CITRATE	11822-4303-2	011822433037
SIGNATURE CARE 100Z LEMON MAG CIT	21130-709-38	321130779155
SIGNATURE CARE 100Z CHERRY CIT	21130-165-38	321130789710
Sound Body 100z lemon mag cit	50594-166-38	072785114791

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Affected Brand NDC # UPC # SUNMARK 100Z LEMON MAG CIT 70677-0051-1 010939908445 SUNMARK 10OZ CHERRY CIT 70677-0053-1 010939910448 SWAN 100Z LEMON MAG CITRATE 0869-0166-38 072785134058 SWAN 100Z CHRY CITRATE 0869-0164-38 308690693381 TOPCARE 100Z LEMON MAG CITRATE 36800-709-38 036800455290 TOPCARE 100Z CHERRY CIT 36800-164-38 036800455306 UP&UP 10OZ LEMON MAG CIT 11673-708-38 072785128835 072785128835 UP&UP 10OZ LEMON MAG CIT 11673-666-38 311917201603 WALGREENS 100Z LEMON MAG CIT 0363-8166-38 WALGREENS 10OZ CHERRY CIT 0363-8164-38 311917201580 WALGREENS 100Z GRAPE MAG CIT 0363-7162-38 311917201597

The product was distributed Nationwide to wholesale and retail outlets. Vi-Jon, LLC is continuing their investigation into the cause of the problem.

Vi-Jon, LLC is notifying its customers by phone and email and is arranging for return or destruction 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 (<u>Recalls@Vijon.com</u>) 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. <u>www.vijon.com</u>.

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 <u>Online</u>
- Regular Mail or Fax: <u>Download form</u> 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**.

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