

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

Company Contact:

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FOR IMMEDIATE RELEASE – July 14, 2022 – Smyrna, TN, Vi-Jon, LLC is expanding its voluntary recall to include all lots of Magnesium Citrate Saline Laxative Oral Solution Lemon Flavor, 10 FL OZ (296 mL) within expiry to the consumer level. The recall was initiated after 3rd Party and Vi-Jon, LLC 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 has received one report of an adverse reaction potentially related to this recall. Vi-Jon, LLC is in the process of investigating this report.

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.

The affected brands of Magnesium Citrate Laxative Oral Solution Lemon Flavor manufactured at Vi-Jon, LLC in Smyrna, TN are:

Affected Brand	NDC#	UPC #
BEST CHOICE 100Z LEMON MAG CIT	63941-533-38	070038200499
CARE ONE 100Z LEMON MAG CIT	72476-001-38	341520313226
CARIBA 100Z LEMON MAG CITRATE	67860-166-38	646702057012
CRUZ BLANC 100Z LEMON MAG CIT	N/A	308697403082
CVS 100Z LEMON MAG CIT	63868-929-38	050428335178
CVS 100Z LEMON MAG CIT	69842-983-38	050428305942
DISCOUNT DRUG MART 100Z LEMON MAG CITRATE	53943-166-38	093351028205
EQUALINE 100Z LEMON MAG CIT	41163-709-38	041163500679
EQUATE 100Z LEMON MAG CIT SRP	49035-506-38	681131287142
EXCHANGE SELECT 100Z LEMON MAG CIT	55301-166-38	614299404205
FAMILY WELLNESS 100Z LEMON CITRATE	55319-666-38	032251580826
GOOD SENSE 100Z LEMON MAG CIT	50804-166-38	846036007374



Affected Brand	NDC#	UPC#
HARRIS TEETER 100Z LEMON MAG CITRATE	72036-002-38	072036726124
HEB 100Z LEMON MAG CITRATE	37808-769-38	041220510863
HEALTH MART 100Z LEMON MAG CIT	62011-0380-1	052569142158
KROGER 100Z LEMON MAG CITRATE	30142-899-38	041260001826
LEADER 100Z LEMON MAG CIT	70000-0424-1	096295135541
MAJOR 100Z LEMON MAG CITRATE	0904-6787-44	309046787440
MEIJER 100Z LEMON MAG CIT	41250-708-38	713733459457
PREMIER VALUE 100Z LOW SOD LEM CIT	68016-696-38	840986035302
PUBLIX 100Z LEMON MAG CIT	56062-266-38	041415506732
QUALITY CHOICE 100Z LEMON MAG CIT	63868-929-38	635515901254
REXALL 100Z LEMON MAG CITRATE	55910-183-38	072785134188
RITE AID 100Z LEMON CITRATE	11822-4330-2	011822433006
SIGNATURE CARE 100Z LEMON MAG CIT	21130-709-38	321130779155
SOUND BODY 100Z LEMON MAG CIT	50594-166-38	072785114791
SUNMARK 100Z LEMON MAG CIT	70677-0051-1	010939908445
SWAN 100Z LEMON MAG CITRATE	0869-0166-38	072785134058
TOPCARE 100Z LEMON MAG CITRATE	36800-709-38	036800455290
UP&UP 100Z LEMON MAG CIT	11673-708-38	072785128835
UP&UP 100Z LEMON MAG CIT	11673-666-38	072785128835
WALGREENS 100Z LEMON MAG CIT	0363-8166-38	311917201603

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 (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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.