Magnesium Citrate Expanded Recall and Persistent Shortage

Issue

A national supply disruption has caused an interruption in the dependable availability of **magnesium citrate oral solution**. This Alert follows an earlier PharMerica Clinical Alert detailing the consumer level recall from just *one* manufacturer.

The recall and shortage has expanded to include ALL flavors and lots of magnesium citrate from Vi-Jon — a key supplier of this product — and is currently affecting availability of all potential product. This supplier provides product for multiple companies' private labels (CVS, Equate, Harris Teeter, Major, Rite Aid, Walgreens, etc.).

Products Affected

Magnesium citrate oral solution, Vi-Jon; ALL BRANDS. See FDA Recall Notice for full list of affected products.

Reason for Recall

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.

Estimated Resupply Date(s)

Distributing companies cannot estimate when additional product will be available.

Action Steps

PharMerica Pharmacies

- If orders for affected product were generated and sent to facilities, pharmacy to pick up the affected product.
- Check inventory for affected product, to quarantine and return per pharmacy policy.
- Respond to orders for magnesium citrate oral solution with message to facility for prescriber to provide order for alternative laxative medication (see *Abridged Clinical Considerations* section and *Additional Resources* below).

Facilities

- Check on-hand stock (including E-Kits) for affected NDC, Lot Number and Expiration Dates from PharMerica.
- Check on-hand stock for affected NDC, Lot Number and Expiration Dates for purchases of product from vendors other than PharMerica.
- Remove affected products from all areas and segregate for return to the originating vendor (PharMerica or other pharmacy) and notify *that* vendor of any recalled stock for pick up.
- If adverse reactions or infections are experienced with the use of this product:
 Submit a report online to www.fda.gov/medwatch/report.htm
- Timely contact prescribers to obtain alternative laxative medication orders when magnesium citrate oral solution is prescribed.

Abridged Clinical Considerations*

- Magnesium Citrate is used for colonoscopy bowel prep and for relief of occasional constipation (irregularity).
- Bowel Prep
 - Magnesium Citrate is NOT recommended as part of a bowel preparation by the American Society for Gastrointestinal Endoscopy due to limited efficacy and potential toxicity.
 - o *If* additional bowel preparation is required beyond the usual PEG and bisacodyl options, consider prescription **oral sodium sulfate (Suprep)**.

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Constipation

- Consider alternative therapies within the same therapeutic class *osmotic laxatives* for similar mechanism of action (function by drawing water in the lumen to increase intestinal peristalsis).
 - Magnesium hydroxide (Milk of Magnesia)
 - Oral Chewable tablet Magnesium hydroxide 1,200 mg/tablet
 - o 2 to 4 tablets once daily or in divided doses; do not exceed 4 tablets in 24 hours.
 - Oral Liquid Magnesium hydroxide 400 mg/5 mL
 - o 30 to 60 mL/day once daily at bedtime or in divided doses.
 - Oral Liquid Magnesium hydroxide 800 mg/5 mL
 - o 15 to 30 mL/day once daily at bedtime or in divided doses.
 - Oral Liquid Magnesium hydroxide 1,200 mg/5 mL
 - 10 to 20 mL/day once daily at bedtime or in divided doses.
 - *NOT good for bowel prep because it is opaque*
 - Lactulose (Kristalose)
 - Oral: 10 to 20 g (15 to 30 mL or 1 to 2 packets) daily; may increase to 40 g (60 mL or 2 to 4 packets) daily if necessary.
 - Sodium phosphate (Fleet Enema)
 - Rectal: Contents of one 4.5 oz enema as a single dose.
 - Polyethylene Glycol 3350 (MiraLAX)
 - Oral: 17 g (~1 heaping tablespoon) dissolved in 120 to 240 mL (4 to 8 ounces) of beverage, once daily.

Additional Resources

- FDA Recall Notification: VI-Jon, LLC Expands Voluntary Worldwide Recall of All Flavors and Lots within Expiry of Magnesium Citrate Saline Laxative Oral Solution Due to Microbial Contamination
- ASHP Recall Notification: Magnesium Citrate Oral Solution

^{*}Information provided herein is purposefully abbreviated for clarity. Please refer to products' full prescribing information for complete details prior to prescribing any pharmaceutical product.