NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2017-10 **AUGUST 17, 2017**

ITEM: **Magnesium Citrate Recall Due to Product Contamination**

SPECIFIC INCIDENT(S):

Vi-Jon, Inc., is recalling specific lots of magnesium citrate solution due to four complaints of matter described as mold that were observed in two product lots. The organism was identified as Rhinocladiella similis.

GENERAL INFORMATION:

- Magnesium citrate solution is a saline laxative used to relieve occasional constipation.
- Contamination with mold may result patient infection or harm. According to the manufacturer, there have been no adverse events reported at this time.
- Affected products include:

Material Description	Item Number	Manufacturer NDC/UPC	LOT # - Expiration Date	Manufacturer Initial Ship Date
CITRATE MAGNESIUM LEMON 12X10OZ CMS	10053603	0869068638	0341906 - 12/31/2018 0343709 - 01/31/2019	02/02/2017
MAG CITRATE SOL LEMON 12X10OZ DS ONC	10143348	0869068638	0341906 - 12/31/2018 0343709 - 01/31/2019	02/02/2017

- This is an extension of the product sequestration actions in **Product Recall Office Log # 12206** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of magnesium citrate solution product(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, gastroenterologists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have

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authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 08/31/2017):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to take the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
  - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: Manufacturer

REFERENCE(S): Amerisource Bergen [Data on file, Date 08/03/17]. Manufacturer Recall, written communication, August 2017.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.