



Clifton Health Department Food Recall Notification



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Food/Drug/Pet Recall: Plastikon Healthcare, LLC

Plastikon Healthcare, LLC is voluntarily recalling Milk of Magnesia 2400 mg/30 mL Oral Suspension, lots 19027D and 19027E, to the patient level. Plastikon Healthcare initiated this recall because these product lots did not meet Plastikon's in-house microbiological specification for Total Aerobic Microbial Count.

This product is packaged for institutional use and is sold to clinics and hospitals, the patient population most likely to use the product are likely immunocompromised. Patients with compromised immune systems, such as patients in hospitals and nursing homes, have a higher probability of developing potentially life-threatening infections after taking a contaminated product. To date, Plastikon has not received any customer complaints or reports of adverse events related to this issue. Milk of Magnesia 2400 mg/ 30 mL is indicated for the occasional relief of constipation (irregularity) in adults and children 12 years and older or for children under 12 as recommended by a doctor.

Milk of Magnesia 2400 mg/ 30 mL Oral Suspension is privately labeled by Major Pharmaceuticals® and packaged in cartons as indicated below. The affected lots were distributed to Major Pharmaceuticals Distribution Center (wholesaler), who may have shipped to clinics, hospitals and healthcare providers, in the United States, in August 2019.

Carton NDC Lot Number Expiration Date Strength Configuration/Count

0904-6846-73 19027D 2021 July 2400 mg/30 mL Carton containing 100 single dose cups (10 trays x 10 cups)

0904-6846-73 19027E 2021 July 2400 mg/30 mL Carton containing 100 single dose cups (10 trays x 10 cups)

Plastikon Healthcare has notified its direct customers via a recall letter to arrange for return of any recalled product.

Anyone with an existing inventory of the lots, which are being recalled, should stop use and distribution and quarantine immediately. Inform healthcare professionals in your organization of this recall. For clinics, hospitals, or healthcare providers that have dispensed product to patients, please notify these patients regarding the recall. For additional assistance, call Plastikon Healthcare at 785-330-7100 (Monday through Friday, 8 a.m. to 5 p.m. CST).

For clinical inquiries, please contact Plastikon Healthcare using the below information.

Contact Center Contact Information Area of Support

Plastikon Healthcare 816-721-3269 (24 hours a day 7 days per week) To report adverse events



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or product complaints

Patients who are taking this product should consult with their healthcare provider or pharmacy to determine if they have the affected product lots. Patients with the affected lots should return the product to their pharmacy or contact Plastikon Healthcare (785-330-7100) for instructions on how to return their product and obtain reimbursement for their cost. 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.