Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Plastikon Healthcare, LLC

Plastikon Healthcare, LLC is voluntarily recalling three (3) lots of Milk of Magnesia 2400 mg/30 mL Oral Suspension, one (1) lot of Acetaminophen 650mg/ 20.3mL, and six (6) lots of Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/Simethicone 120mg per 30 mL to the hospital, clinic and patient level. The products are being recalled due to microbial contamination and failure to properly investigate failed microbial testing.

Risk Statement: This product potentially could result in illness due to intestinal distress, such as diarrhea or abdominal pain. Individuals with a compromised immune system have a higher probability of developing a wide-spread, potentially life-threatening infection when ingesting or otherwise orally exposed to products contaminated by micro-organisms. To date, Plastikon has not received any customer complaints related to microbial concerns or reports of adverse events related to this recall.

Product indication, lot numbers, expiration dates and NDC information are listed in the table below. The product is packaged for institutional use and is sold to clinics and hospitals nationwide in single use cups with a foil lid. The affected lots were distributed to Major Pharmaceuticals Distribution Center (wholesaler) between 5/1/2020 and 6/28/2021, who shipped to hospitals, nursing homes, and clinics nationwide. The products are private labeled for Major Pharmaceuticals.

Product Name	Milk of Magnesia 2400 mg/30 mL Oral Suspension	Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/Simethicone 120mg per 30 mL	Acetaminophen 650mg/ 20.3mL
Indications for use	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.	Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/Simethicone 120mg per 30 mL is indicated for relief of acid indigestion, heartburn, sour stomach, upset stomach due to these symptoms, pressure and bloating commonly referred to as gas.	Acetaminophen 650mg/ 20.3mL indicated for temporarily relief of minor aches and pains due to, minor pain of arthritis, muscular aches, backache, premenstrual and menstrual cramps, the common cold, headache, toothache, and temporarily reduction of fever.
Lot/exp.	20024A/Mar 2022 20025A/Mar 2022 20041A/May 2022	20042A/May 2022 20043A/May 2022 20045A/May 2022 20046A/May 2022 20047A/May 2022	20040A/May 2022

		21067A/Jun 2023	
NDC	0904-6846-73	0904-6838-73	0904-6820-76
Type of Packaging	Carton containing 100 single dose cups (10 trays x 10 cups)	Carton containing 100 single dose cups (10 trays x 10 cups)	Carton containing 100 single dose cups (10 trays x 10 cups)

Plastikon Healthcare places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. 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. Return all quarantined product to the place of purchase. For clinics, hospitals, or healthcare providers that have dispensed product to patients, please notify patients regarding the recall.

Consumers with questions regarding this recall can contact Plastikon by phone at 785-330-7109 or email address (**sdixon@plastikon.com**) Monday through Friday from 9 am to 4 pm CST. Patients are advised to contact their doctor 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.