COMPANY ANNOUNCEMENT

Plastikon Healthcare Issues Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension 2400 mg/30 mL due to Microbial Contamination

Summary

Company Announcement Date:

September 06, 2019

FDA Publish Date:

September 09, 2019

Product Type:

Drugs

Reason for Announcement:

Microbial Contamination

Company Name:

Plastikon Healthcare

Brand Name:

Major Pharmaceuticals

Product Description:

Milk of Magnesia Oral Suspension 2400 mg/30 ml

Company Announcement

Lawrence, KS, 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 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. 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 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/forms-reporting-fda) 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.

Company Contact Information

Consumers:

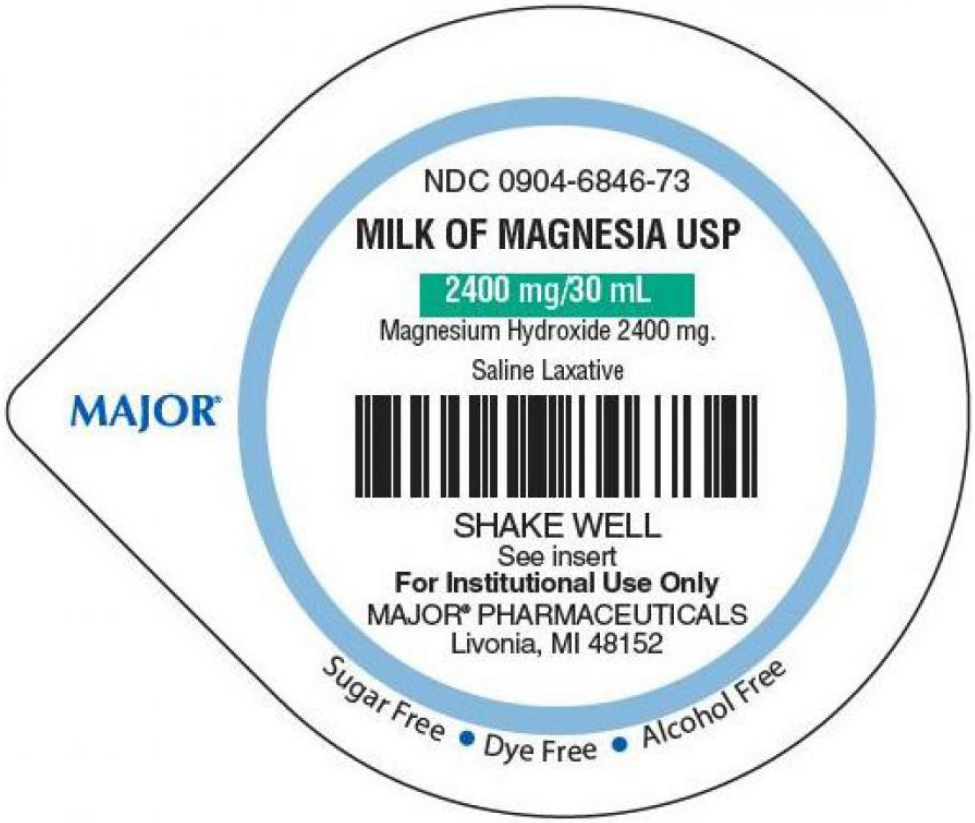
Plastikon Healthcare

785-330-7100

Media:

800-370-0858

Product Photos


NDC 0904-6846-73
MILK OF MAGNESIA USP
2400 mg/30 mL
Magnesium Hydroxide 2400 mg.
Saline Laxative
MAJOR®
SHAKE WELL
See insert
For Institutional Use Only
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Sugar Free • Dye Free • Alcohol Free

Product Insert

Milk of Magnesia, USP

NDC 0904-6846-73

10 x 30 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 30 mL cup)	Purpose
Magnesium hydroxide USP 2400 mg	Saline laxative

Uses ■ relieves occasional constipation (irregularity)
■ generally produces bowel movement in ½ to 6 hours

Warnings

Ask a doctor before use if you have

■ kidney disease ■ a magnesium-restricted diet
■ stomach pain, nausea, or vomiting
■ a sudden change in bowel habits that lasts more than 2 weeks

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if ■ you have rectal bleeding or no bowel movements after using this product. These could be signs of a serious condition.
■ you need to use a laxative for more than 1 week

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

■ do not exceed the maximum recommended daily dose in a 24 hour period
■ shake well before use
■ dose may be taken once a day preferably at bedtime, or as directed by a doctor
■ drink a full glass (8 oz) of liquid with each dose

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 60 mL in 24 hrs.
children under 12 years	ask a doctor

Other information

■ **each 30 mL contains:** calcium 40 mg, sodium 100 mg, and magnesium 1000 mg
■ store at 20-25°C (68-77°F) ■ protect from excessive moisture
■ do not use if lid seal is open or damaged ■ sugar free, dye free, alcohol free
■ see bottom of cup for lot number and expiration date

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xanthan gum

Questions or comments?

Call 1-800-616-2471

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