DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Plastikon Healthcare Issues Voluntary Nationwide Recall of Milk of Magnesia Oral Suspension and Magnesium Hydroxide /Aluminum Hydroxide /Simethicone Oral Suspension Due to Microbial Contamination

6/07/2022 – Lawrence, Kansas – Plastikon Healthcare, LLC is voluntarily recalling one (1) lot of Milk of Magnesia 2400 mg/10 mL Oral Suspension, one (1) lot of Milk of Magnesia 2400 mg/30 mL Oral Suspension, eleven (11) lots of Magnesium Hydroxide 1200 mg/Aluminum Hydroxide 1200 mg/Simethicone 120 mg per 30 mL Oral Suspension, and two (2) lots of Magnesium Hydroxide 2400 mg/Aluminum Hydroxide 2400 mg/Simethicone 240 mg per 30 mL Oral Suspension to the consumer level. The products are being recalled due to microbial contamination.

Risk Statement: Administration or use of oral drug products with microbial contamination could potentially result in increased infections that may require medical intervention. 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 Healthcare has not received any reports of adverse events or injuries related to this recall.

Product indication, lot numbers, expiration dates, and NDC information are listed in the table below. The products are packaged for institutional use and are 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 7/1/2020 and 10/31/2021, 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	Milk of Magnesia 2400 mg / 10 mL Oral Suspension	Magnesium Hydroxide 1200 mg / Aluminum Hydroxide 1200 mg / Simethicone 120 mg per 30 mL Oral Suspension	Magnesium Hydroxide 2400 mg / Aluminum Hydroxide 2400 mg / Simethicone 240 mg per 30 mL Oral Suspension
Indications for Use	Occasional relief of constipation (irregularity) in adults and children 12 years and older or for children under 12 as recommended by a doctor.	Occasional relief of constipation (irregularity) in adults and children 12 years and older or for children under 12 as recommended by a doctor.	Relief of acid indigestion, heartburn, sour stomach, upset stomach due to these symptoms, pressure and	Relief of acid indigestion, heartburn, sour stomach, upset stomach due to these symptoms, pressure and

			bloating commonly referred to as gas.	bloating commonly referred to as gas.
Lot/Exp.	20071A / Jul. 2022	20074A / Jul. 2022	21103A / Sep. 2023 20046A / May. 2022 20079A / Aug. 2022 20080A / Aug. 2022 20081A / Aug. 2022 21057A / May. 2023 21059A / May. 2023 21095A / Sep. 2023 21096A / Sep. 2023 21099A / Sep. 2023 21115A / Oct. 2022	20051A / Aug. 2022 20088A / Sep. 2022
NDC	0904-6846-73	0904-6840-72	0904-6838-73	0904-6839-73
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)	Carton containing 100 single dose cups (10 trays x 10 cups)
Product Identification	See image below	See image below	See image below	See image below

Plastikon Healthcare is notifying 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 Healthcare by phone at (785) 330-7109 or by e-mail at sdixon@plastikon.com Monday through Friday from 9 am to 4 pm CST. 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:** www.fda.gov/medwatch/report.htm

- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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
785-330-7109
sdixon@plastikon.com

Product Photos

Product Insert

Magnesium hydroxide/Aluminum hydroxide /Simethicone

NDC 0904-6838-73
10 x 30 mL Unit Dose Cups

Drug Facts

Active ingredients (in each 30 mL cup)	Purpose
Aluminum hydroxide (equiv. to dried gel, USP) 1200 mg	Antacid
Magnesium hydroxide USP 1200 mg	Antacid
Simethicone 120 mg	Antigas

Uses ■ acid indigestion ■ heartburn ■ sour stomach ■ upset stomach due to these symptoms ■ pressure and bloating commonly referred to as gas

Warnings

Ask a doctor before use if you have
■ kidney disease ■ a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if ■ you have symptoms that last more than 2 weeks

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)

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

Directions

■ do not exceed the maximum recommended daily dose in a 24 hour period
■ shake well before use
■ do not use the maximum daily dose for more than 2 weeks

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 120 mL in 24 hours
children under 12 years	ask a doctor

Other information

■ **each 30 mL contains:** calcium 40 mg, sodium 25 mg, and magnesium 500 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, sucralose, sodium citrate, spearmint oil, xanthan gum

Questions or comments?
Call 1-800-616-2471

MAJOR®

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Re-order
No. 701031

M-154
C05035 R1
Rev. 04/19


MAJOR
NDC 0904-6838-73
Each 30 mL Contains:
Magnesium Hydroxide 1200 mg
Aluminum Hydroxide 1200 mg
Simethicone 120 mg
Delivers 30mL
SHAKE WELL
See insert
For Institutional Use Only
MAJOR® PHARMACEUTICALS
Livonia, MI 48152
Sugar Free • Dye Free • Alcohol Free

Product Insert

Magnesium hydroxide/Aluminum hydroxide /Simethicone Max

NDC 0904-6839-73
10 x 30 mL Unit Dose Cups

Drug Facts

Active ingredients (in each 30 mL cup)	Purpose
Aluminum hydroxide (equiv. to dried gel, USP) 2400 mg	Antacid
Magnesium hydroxide USP 2400 mg	Antacid
Simethicone 240 mg	Antigas

Uses ■ acid indigestion ■ heartburn ■ sour stomach ■ upset stomach due to these symptoms ■ pressure and bloating commonly referred to as gas

Warnings

Ask a doctor before use if you have
■ kidney disease ■ a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if ■ you have symptoms that last more than 2 weeks

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)

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

Directions

■ do not exceed the maximum recommended daily dose in a 24 hour period
■ shake well before use
■ do not use the maximum daily dose for more than 2 weeks

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

Other information

■ **each 30 mL contains:** calcium 40 mg, sodium 25 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, sucralose, sodium citrate, spearmint oil, xanthan gum

Questions or comments?

Call 1-800-616-2471

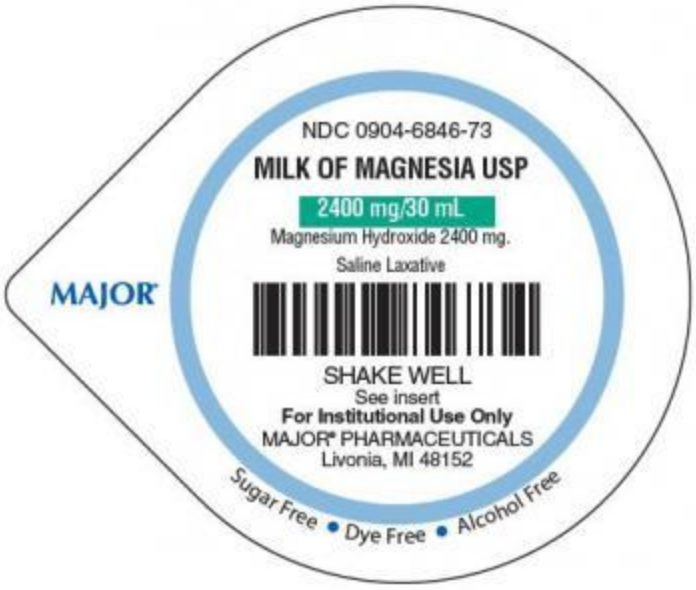
MAJOR®

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Re-order
No. 701032

M-154
C05036 R1
Rev. 04/19

- 
NDC 0904-6839-73
Each 30 mL Contains:
Magnesium Hydroxide 2400 mg
Aluminum Hydroxide 2400 mg
Simethicone 240 mg
MAX
Delivers 30 mL
MAJOR
SHAKE WELL
See insert
For Institutional Use Only
MAJOR® PHARMACEUTICALS
Livonia, MI 48152
Sugar Free • Dye Free • Alcohol Free
- 
NDC 0904-6840-72
MILK OF MAGNESIA
CONCENTRATE
2400 mg/10 mL
Magnesium Hydroxide 2400 mg.
Saline Laxative
MAJOR
SHAKE WELL
See insert
For Institutional Use Only
MAJOR® PHARMACEUTICALS
Livonia, MI 48152
Sugar Free • Dye Free • Alcohol Free
-


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
MAJOR® PHARMACEUTICALS
Livonia, MI 48152
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 108 mg, and magnesium 1068 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

MAJOR
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Re-order No. 703034

M-154
C05020 R8
Rev. 03/19

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- Source:https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-issues-voluntary-nationwide-recall-one-lot-anagrelide-capsules-usp-05-mg-due-dissolution-test?utm_medium=email&utm_source=govdelivery