

Plastikon Healthcare – Recall of magnesium hydroxide/aluminum hydroxide/simethicone

- On August 4, 2022, the [FDA announced](#) an update to the voluntarily consumer-level recall of Plastikon Healthcare’s [magnesium hydroxide/aluminum hydroxide/simethicone](#) initiated on June 3, 2022 to include lot 20076A. This lot is being recalled due to microbial contamination.
- The list below includes all products recalled as of June 3, 2022, including the additional lot. These were distributed between July 2020 and October 2021.

Product Description	NDC#	Lot# (Expiration Date)
Milk of Magnesia 2400 mg/30 mL oral suspension	0904-6846-73	20071A (7/2022)
Milk of Magnesia 2400 mg/10 mL oral suspension	0904-6840-72	20074A (7/2022)
Magnesium hydroxide 1200 mg/ aluminum hydroxide 1200 mg/ simethicone 120 mg per 30 mL oral solution	0904-6838-73	21103A (9/2023); 20046A (5/2022); 20076A (7/2022); 20079A (8/2022); 20080A (8/2022); 20081A (8/2022); 21057A (5/2023); 21059A (5/2023); 21095A (9/2023); 21096A (9/2023); 21099A (9/2023); 21115A (10/2022)
Magnesium hydroxide 2400 mg/ aluminum hydroxide 2400 mg/ simethicone 240 mg per 30 mL oral solution	0904-6839-73	20051A (8/2022); 20088A (9/2022)

- Milk of Magnesia is indicated for the occasional relief of constipation in adults and children 12 years and older or for children under 12 as recommended by a doctor.
- Magnesium hydroxide/aluminum hydroxide/simethicone is indicated for relief of acid indigestion, heartburn, sour stomach, upset stomach due to these symptoms, pressure and bloating commonly referred to as gas.
- Administration or use of 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.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- To date, Plastikon Healthcare has not received any reports of adverse events or injuries related to this recall.
- Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking or using Plastikon Healthcare's recalled products.
- Contact Plastikon by phone at **1-785-330-7109** or by email at **dixon@plakiston.com** for more information about the recall.



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