

Ascent Consumer Products – Recall of SinuCleanse[®] Soft Tip Squeeze Bottle Nasal Wash System

- On February 25, 2025, <u>Ascent Consumer Products announced</u> a consumer level recall of one lot of <u>SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System</u> because of a confirmed test result of microbial contamination of the product with <u>Staphylococcus aureus</u> (S. aureus).
- SinuCleanse was distributed nationwide in January 2025.

Product Description	NDC#	Lot# (Expiration Date)
SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System, squeeze bottle and 30 saline packets	46011-0001-04	024122661A1 (12/31/2027)

- SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System is used as a nasal wash of the nasal passages to help temporarily relieve symptoms associated with sinusitis, cold, flu, or allergies.
- Use of the SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System, contaminated with *S. aureus*, can result in blood infections in users whose nasal mucosa may be compromised due to inflammation and mechanical injuries, caused by nasal irrigation. Resulting secondary infections may occur, such as endocarditis, bone and joint infections, splenic abscesses or meningitis, and bacterial sinusitis which may lead to eye tissue infections, vision problems, cranial nerve damage, or meningitis. These infections are serious and potentially life-threatening.
- To date, Ascent Consumer Products has not received any reports of adverse events related to this recall.
- Anyone with the affected lot on hand should stop distribution and return product. Patients that
 have bottles from the recalled lot of SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System
 should stop using the product and return the product to the place of purchase or discard it.
- Patients should contact their physician or healthcare provider if they experience any problems related to the use of this product.
- Contact Ascent Consumer Products by email at <u>cs@ascentconsumerproducts.com</u> for questions regarding this recall.



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