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Class 2 Device Recall NasoGel Spray



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Class 2 Device Recall NasoGel Spray



Date Initiated by Firm	December 28, 2024
Date Posted	February 05, 2025
Recall Status ¹	Open ³ , Classified
Recall Number	Z-1105-2025
Recall Event ID	96076 ²³
Product Classification	Applicator, ent ²⁴ - Product Code KCJ ²⁵
Product	NeiMed NasoGel for DRY NOSES UDI-DI/UPC code: 00705928045309 SKU GSP30-2R-48-ENU-USL GSP30-0R-96-ENU-USL GSP30-ARA-INTL GSP30-SWE-INTL GSP30-ENG-INT GSP30-MAL-INTL GSP30-SPA-INT

NasoGel Spray is a saline-based gel formula that can be sprayed to moisturize and lubricate dry and irritated anterior or front of nasal passages caused by dry climate and indoor heat.

Code Information

NasoGel Spray
 UDI-DI/UPC code: 00705928045309
 SKU / Lot Numbers:
 GSP30-2R-48-ENU-USL / NGS751

GSP30-0R-96-ENU-USL / NGS757 and NGS762

GSP30-ARA-INTL / NGS762

GSP30-SWE-INTL / NGS754

GSP30-ENG-INT / NGS755

GSP30-MAL-INTL / NGS756

GSP30-SPA-INT / NGS760 and NGS761

**Recalling Firm/
Manufacturer**

Neilmed Pharmaceuticals Inc
 601 Aviation Blvd
 Santa Rosa CA 95403-1025

**For Additional
Information Contact**

Customer Service
 877-477-8633

**Manufacturer Reason
for Recall**

Due to nasal spray stability failure for bioburden.

**FDA Determined
Cause ²**

Under Investigation by firm

Action

On 12/28/2024, the firm sent an "URGENT: MEDICAL DEVICE RECALL" Letter to customers informing them that firm is conduct a voluntary recall due to a microbial failure found during routine stability testing and the receipt of complaints (11 reports) related to the products unpleasant odor. Through investigation, this has led to the recall of 3 lots. We started shipping these lots in April 2024.

Customer are instructed to:
 Immediately examine their inventory and quarantine products subject to recall and destroy the identified lots. In addition, if the affected products have been further distributed, please identify the consumers and notify them at once of this product recall. A copy of this recall notification letter may enhance your notification to your

consumers.

The firm will provide customers with a refund or product replacement at no cost.

Please send us the proof of destruction via email to quality@neilmed.com.

For any questions, contact Dinesh Patel. M F, 8:00 am - 5:00 pm PST, (707) 889-4625.

On or about 02/06/2025, the firm added a Recall Statement to its company website <https://shop.neilmed.com/products/nasogel-spray> that reads "Recall Notice: NeilMed is voluntarily recalling NasoGel Spray lots NGS751, NGS757, and NGS762 distributed in 2024 due to potential contamination, which may lead to symptoms similar to the flu. If your product is affected, please email questions@neilmed.com and put NGS-PA in the subject for further instructions .

Quantity in Commerce 89,312

Distribution Worldwide - U.S. Nationwide distribution in the states of AL, AZ, CA, CO, CT, FL, GA, ID, IL, IN, KY, MA, MD, MI, MN, MO, NC, NJ, NM, NY, OH, OR, PA, RI, SC, TN, TX, VA, VT, WA, and WI. The countries of Bahrain, Ireland, Malaysia, Mexico, and United Kingdom.

Total Product Life Cycle [TPLC Device Report](#)²⁶

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁷.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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