cicasereports.org

Clinical Imaging and Case Reports

ISSN 2770-9205

Case Report

Real-World Performance, Tolerability And User Acceptance Of A Hypertonic Seawater Nasal Spray Containing Hyaluronic Acid And Dexpanthenol For Nasal Mucosal Hydration And Symptom Relief: A Multicentre Post-Market User Survey.

Sentiljana Gumeni[1], Konstantinos Alevizopoulos[1]*

[1]Gerolymatos International SA, Asklipiou 8, Kryoneri 14568, Greece.

Abstract

Nasal mucosal dryness and nasal obstruction are frequent complaints in allergic and infectious rhinitis, during the common cold and influenza, following endonasal surgery, in low-humidity or air-conditioned environments, and in rhinitis sicca, including medication-induced mucosal drying. Seawater-based nasal sprays are widely used as non-pharmacological means to enhance mucosal hydration and support mucociliary clearance. This study aimed to characterize symptom evolution, onset of relief, tolerability, device performance and user acceptance of a hypertonic seawater nasal spray containing hyaluronic acid and dexpanthenol (herein HSHD) under routine conditions of use in 252 subjects. In the 160 participants with complete scores, the Composite Total Symptom Score (CTSS) decreased from 30.2 ± 13.6 to 11.9 ± 9.6 (mean reduction 18.3 points, 60.5%; $p < 0.001$). Improvement after the use of HSHD was reported within 30 minutes of administration by 189/239 patients (79.1%) and within the first three days of use by 220/237 (92.8%). Adverse events were reported by 8/252 participants (3.2%), all local (nasal irritation, epistaxis and stinging sensation). All respondents rated the device easy to use (237/237, 100%) and 97.9% (230/235) would recommend or repurchase it; no device malfunctions were reported. Overall, these data support the performance, safety and usability of HSHD under routine conditions of use.

Keywords: *Seawater nasal spray; Nasal dryness; Rhinitis sicca; Nasal congestion; Real-world evidence; Hyaluronic acid; Dexpanthenol.*

INTRODUCTION

Approximately 12,000 liters of air pass through the adult nose each day, where the nasal mucosa warms, humidifies, and filters inspired air through the coordinated function of the airway surface liquid and ciliated epithelium [1]. The airway surface liquid comprises two distinct layers: a periciliary layer of approximately 6 µm, in which cilia beat, and an overlying mucus gel layer that traps inhaled particles. Mucociliary clearance is optimal at approximately 37°C and 100% relative humidity, while the depth and rheological properties of these layers are influenced by mucosal hydration [1]. Depletion of the airway surface liquid increases mucus viscosity and impairs mucociliary clearance, potentially resulting in nasal dryness, crusting, obstruction, itching, and reduced olfactory function [1,2].

Nasal dryness is a common feature of several clinical and environmental conditions. It may occur in low-humidity environments, including air-conditioned or heated indoor settings, as well as in conditions such as allergic and infectious rhinitis, the common cold, influenza, and rhinosinusitis [3,4]. Nasal dryness may also develop following endonasal or sinus surgery, particularly during the early postoperative period when crusting and impaired mucociliary clearance are common [5]. In addition, it is a recognized adverse effect of certain pharmacological treatments, including prolonged use of topical decongestants, systemic or topical antihistamines, and intranasal corticosteroids, and may contribute to the clinical presentation of rhinitis sicca [6]. Nasal dryness, beyond causing local discomfort, can affect sleep and may contribute

***Corresponding Author:** Alevizopoulos K.** Gerolymatos International SA, Kryoneri, Greece. **Email:** kalevizo@gerolymatos-int.com.
Received: 26-October-2026, Manuscript No. CICR - 6328 **; Editor Assigned:** 27-October-2026 **; Reviewed:** 13-November-2026, QC No. CICR - 6328 **;**
Published: 18-November-2026. **DOI:** 10.52338/cicasrep.2026.6328.
Citation: **Gumeni S and Alevizopoulos K.** Real-World Performance, Tolerability And User Acceptance Of A Hypertonic Seawater Nasal Spray Containing Hyaluronic Acid And Dexpanthenol For Nasal Mucosal Hydration And Symptom Relief: A Multicentre Post-Market User Survey. Clinical Imaging and Case Reports. 2026 November; 20(1). doi: 10.52338/cicasrep.2026.6328.
Copyright © 2026 **Gumeni S and Alevizopoulos K.** This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

to fatigue, reduced productivity, and impaired emotional well-being. These effects are well known in allergic rhinitis, where nasal obstruction has been associated with impaired sleep quality [7], as well as in rhinosinusitis, where impaired quality of life represents an important component of disease burden [3,4].

Seawater- and saline-based nasal sprays and irrigations (SNI) are often used to increase local nasal hydration. By replenishing the airway surface liquid, SNI can facilitate hydration of the mucosa, soften and mobilize nasal secretions, and promote the mechanical removal of inflammatory mediators, allergens, and pathogens from the mucosal surface. These effects support physiological mucociliary clearance and contribute to the restoration of normal nasal function. SNI is recommended as an adjunctive measure in the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2020) and is incorporated into ARIA-based management approaches for allergic rhinitis. Clinical studies have also reported symptomatic benefits in acute upper respiratory tract infections, allergic rhinitis, and chronic rhinosinusitis, with a generally favorable tolerability profile [3,4,8–11].

Notably, the formulation and tonicity of SNI may influence their effects on the nasal mucosa. Hypertonic solutions generate an osmotic gradient across the mucosa, promoting the movement of water into the nasal lumen and thereby reducing mucosal oedema and decreasing mucus viscosity [12]. However, for products intended specifically to manage nasal dryness, any decongestant effect should be complemented by the ability to restore and maintain moisture at the nasal epithelial surface, where the airway surface liquid may already be depleted.

Sodium hyaluronate and dexpanthenol are among the excipients commonly used in nasal formulations to increase hydration. Sodium hyaluronate is a hygroscopic glycosaminoglycan that is naturally present in the airway surface liquid. Through its water-retaining properties, it can increase hydration at the epithelial surface, while also contributing to the maintenance of epithelial integrity [13]. Dexpanthenol, the alcohol analogue of pantothenic acid (vitamin B5) and a precursor of coenzyme A, has been shown to retain water, providing local hydration and promoting natural regeneration of the nasal mucosa [14]. A randomized study reported that nasal sprays containing hyaluronic acid, with or without dexpanthenol, improve symptoms of nasal dryness compared with isotonic saline in patients with rhinitis sicca [6]. In addition, a hyaluronic acid–dexpanthenol formulation was associated with a trend towards improved mucosal regeneration following septoplasty, ethmoid, and turbinate surgery, without statistically significant differences from standard care [5].

The present study aimed to evaluate the use of a nasal formulation containing hypertonic seawater, sodium hyaluronate, and dexpanthenol in individuals with conditions associated with nasal dryness for which the formulation is intended. Specifically, we aimed to quantify changes in nasal and nasal-related systemic symptoms following product use, characterize the onset of symptom relief and patterns of use, assess tolerability and device performance, and evaluate user acceptance.

METHODS

Medical device

The product evaluated in this study is SINOMARIN DRY NOSE RELIEF SPRAY; Gerolymatos International S.A (hereafter "HSHD"), a hypertonic seawater nasal spray containing a 2.3% NaCl seawater solution with its native mineral salts and trace elements, purified water, sodium hyaluronate and dexpanthenol. The formulation contains no drug substances, preservatives or other additives. It is CE-marked as a Class IIa medical device.

The same formulation is supplied in two delivery formats, both of which were represented in this survey:

- a 30 mL mechanical pump spray, delivering a fixed dose by manual pump actuation, labelled for use from 6 years of age;
- a 100 mL bag-on-valve (BOV) continuous-flow spray, delivering a propellant-driven continuous spray, labelled for use from 12 years of age.

Survey patients and design

This real-world, prospective user survey was conducted in Hungary between November 2025 and March 2026 and enrolled 252 adult and pediatric patients. Eligible participants were patients with nasal complaints to whom the device was recommended and supplied by a collaborating physician or pharmacist. Participants completed the questionnaire before first use and after a period of use (typically 7–14 days), either independently or, for pediatric users, with the assistance of a parent, caregiver or healthcare professional. No restriction was applied by indication, disease severity or concomitant medication, to preserve the representativeness of the real-world user population. Each patient completed a structured questionnaire at two time points: before the first use of the nasal spray and after a period of use. The survey was conducted as post-market clinical follow-up of a CE-marked medical device in accordance with Regulation (EU) 2017/745 [15] and the corresponding guidance on PMCF methodology [16].

Questionnaire and Outcome Measures

A single structured questionnaire, identical across collection points, was used. It comprised four parts.

Symptom assessment. Ten domains were rated using a 0–6 Likert scale (0 = not troubled, 6 = extremely troubled), for the period before product use and for the period after use: stuffy nose, runny nose, sneezing, itchy/dry nose, other nasal problems, fatigue, reduced productivity, poor sleep quality, feeling emotionally tired or low, and overall feeling.

Timing and use. Onset of perceived relief after a single administration (less than 5 minutes, up to 30 minutes, more than 30 minutes, no improvement); the day on which improvement was first noticed (1st, 2nd, 3rd day, after 5 days, after 7 days, no improvement); daily frequency of use; timing relative to other medication; and total duration of use in days.

Concomitant medication. Use of other medicated nasal products during the observation period, the products named, whether overall medicated-product intake was perceived to have decreased, and whether the participant would consider using the device without medication. The last two items used a six-point agreement scale from "Absolutely yes" to "Absolutely not".

Tolerability, device performance and acceptance. Occurrence of any adverse event or device malfunction was recorded. Overall satisfaction and perceived efficacy were rated on a six-point scale from 1 ("Extremely dissatisfied") to 6 ("Extremely satisfied"). Ease of use and willingness to recommend or repurchase were assessed on a six-point scale from "Absolutely Yes (1)" to "Absolutely Not (6)".

The questionnaire also recorded demographics and disease condition(s) for which the product was used.

Data analysis

A total of 252 completed questionnaires with symptom-score data were included in the final analysis. Before analysis, the dataset was checked for completeness and internal consistency. For paired before–after comparisons, only participants with valid responses for both corresponding items were included; participants with a missing value for either item of a pair were excluded from that specific comparison only. Where participants simultaneously endorsed mutually exclusive usage-frequency categories, the variable was classified as indeterminate rather than excluded.

A Composite Total Symptom Score (CTSS) was derived, at each time point, as the unweighted arithmetic sum of the ten item scores:

CTSS = stuffy nose + runny nose + sneezing + itchy/dry nose + other nasal problems + fatigue + reduced productivity + poor sleep quality + emotionally tired or low + overall feeling

Each item contributes 0 to 6, so the composite ranges from 0 (no burden in any domain) to 60 (maximum burden in every domain), with all ten domains weighted equally. The CTSS was computed only for participants with all ten items present at both time points (n = 160 of 252).

All analyses were performed with the two device presentations (30 mL and 100 mL) pooled. The formulation is identical in the two, so symptom outcomes are not expected to depend on the delivery device, and pooling preserves the full sample. Device format is addressed in a separate subsection of the Results. Participants were not randomized to the two device variants, and the groups showed differences in age, sex, and baseline symptom severity; therefore, no statistical comparison between device variants was performed. However, the device-dependent endpoints (malfunction, local tolerability and usability) are reported separately for each variant, as proportions with exact 95% confidence intervals.

Statistical analysis

Data were analyzed using Python (version 3) in Jupyter Notebook (version 7.0.8) within the Anaconda distribution, together with standard statistical packages including NumPy and SciPy. Study variables were described using absolute and relative frequencies before and after product use, and continuous variables were summarized as mean (standard deviation) and median (interquartile range). Percentage improvement was calculated as (mean score before − mean score after) / mean score before × 100. Paired before–after comparisons were performed using the Wilcoxon signed-rank test and the paired t-test, as appropriate. The level of statistical significance was set at $\alpha = 0.05$. Between-group comparisons used the Mann–Whitney U test for continuous and ordinal variables, the Kruskal–Wallis test for more than two groups, and Fisher's exact test for proportions [17].

RESULTS

Survey population and product use

A total of 252 patients were enrolled in this study, and paired analyses were performed using all available pre- (247 participants (98.0%)) and post-treatment (238 participants (94.4%)) responses for each domain. Both time points were available for 235 participants (93.3%), and all ten domains at both time points for 160 (Figure 1). Age and device format were each recorded for 248 participants (**Figure 1**). The mean age of participants was 42.7 ± 15.7 years (median, 42; range, 8–88 years, **Figure 2A**). Among the 246 participants with recorded sex, 158 (64.2%) were female and 88 (35.8%) were male (**Figure 2B**). In addition, of the 248 participants with recorded age, seven (2.8%) were younger than 18 years (ages 8, 10, 12, 14, 15, 17, and 17 years), while 112 (45.2%) were aged 18–40 years, 106 (42.7%) were aged 41–65 years, and 23 (9.3%) were older than 65 years. Among participants with both age and sex recorded (n = 243), the female predominance was consistent across the adult age bands: 65% of those aged 18–40 years, 66% of those aged 41–65 years and 70% of those older than 65 years, whereas five of the seven participants under 18 years were male (**Figure 2C**).

Most participants reported a single condition (n=171), whereas 67 reported two or more conditions (**Figure 2D**), comprising 15 distinct combinations (data not shown). The most frequently reported conditions were allergic rhinitis (94/238, 39.5%), nasal dryness (76/238, 31.9%), nasal hygiene and moisturization (73/238, 30.7%), common cold or influenza (30/238, 12.6%), infectious rhinitis (26/238, 10.9%), and recovery following endonasal surgery (10/238, 4.2%). Three participants reported other conditions, while one reported a deviated nasal septum (**Figure 2E**). As these indications were not mutually exclusive, percentages do not sum to 100%.

Regarding product use, the 30 mL pump spray was used by 235 participants (93.3%), while 13 participants (5.2%) used the 100 mL BOV spray (Figure 1). The device format was not specified by 4 participants (1.6%) (data not shown). The mean duration of product use was 9.7 ± 8.7 days (median, 8 days; n=228) (**Figure 3A**). Most participants reported using the product 1-3 times daily (118/252, 46.8%), while 95 (37.7%) reported use >3 times daily (**Figure 3B**). The two frequency options were mutually exclusive on the questionnaire; however, 13 participants (5.2%) selected both options and were therefore classified as having an indeterminate frequency of use. A further 26 participants (10.3%) did not report their frequency of use. Concomitant medicated nasal products were used by 90 participants (35.7%), whereas 147 (58.3%) did not use them and 15 (6.0%) did not answer (**Figure 3C**). Regarding the timing of product use relative to these products, 35 of the 90 users (38.9%) reported using the product before their medication, while 20 (22.2%) reported using it between medication doses. In addition, 37 participants (14.7% of the total study population) reported using the product without a fixed schedule. As this response option did not require concomitant medication use, it was reported for the overall study population (**Figure 3D**).

Figure 1. Participant flow. Flow of participants from returned questionnaires, comprising the safety population, through the paired-analysis and complete-CTSS populations. The age and device-format subgroups are also shown. Item-specific denominators vary because missing values were not imputed.

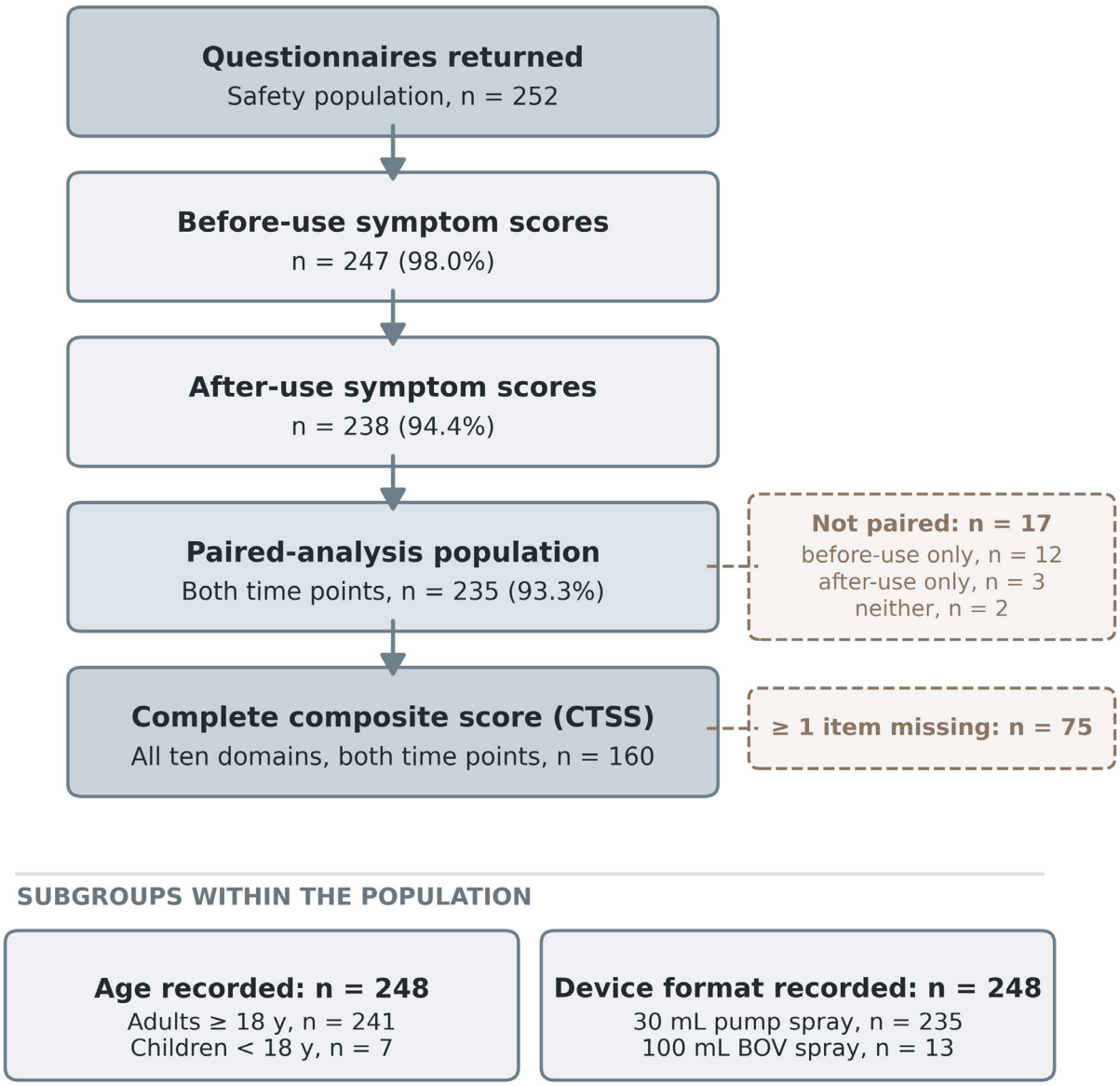


Figure 2. Characteristics of the study population. (A) Age distribution (n = 248), with the mean age shown by the dashed line and the 18-year cut-off by the dotted line. (B) Sex distribution (n = 246). (C) Age distribution by sex (n = 243). (D) Number of indications reported by each participant (n = 238). (E) Indications for use (n = 238). Participants could report more than one indication, and therefore percentages do not sum to 100%.

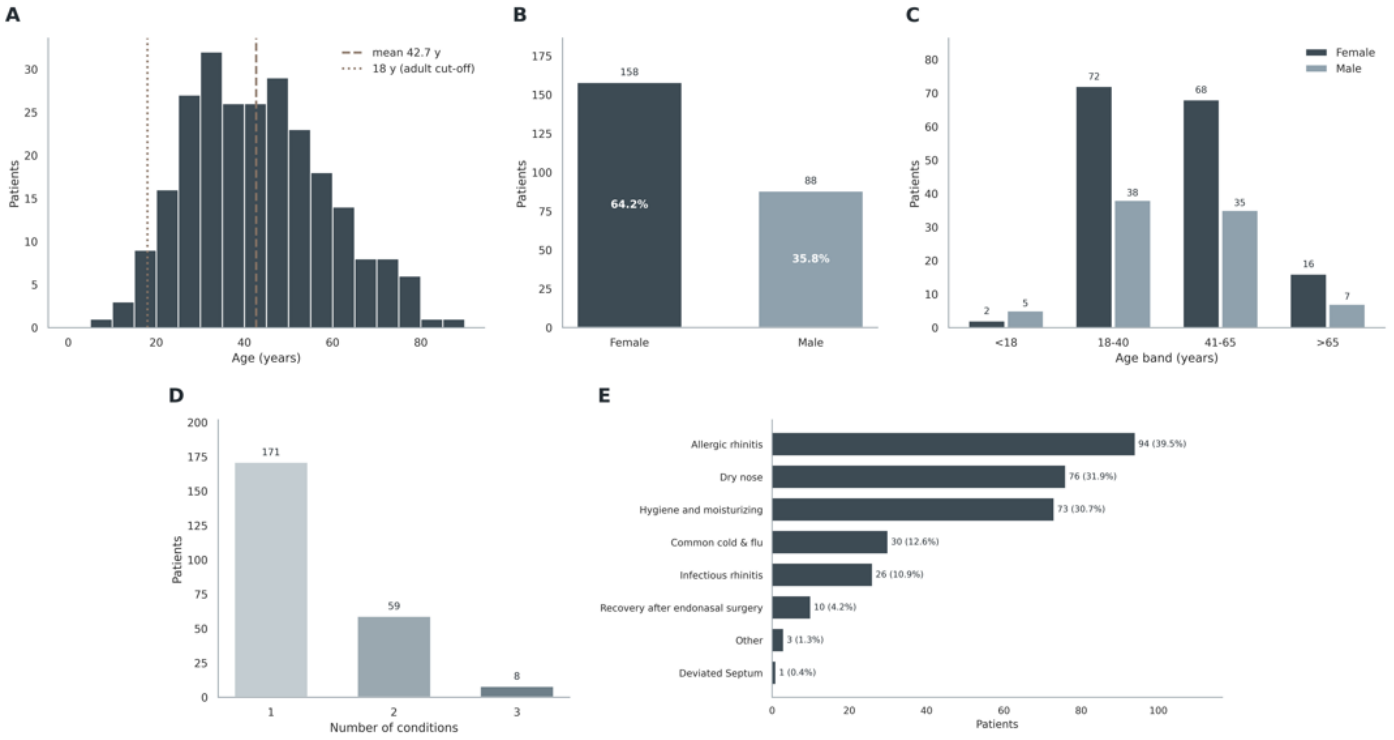
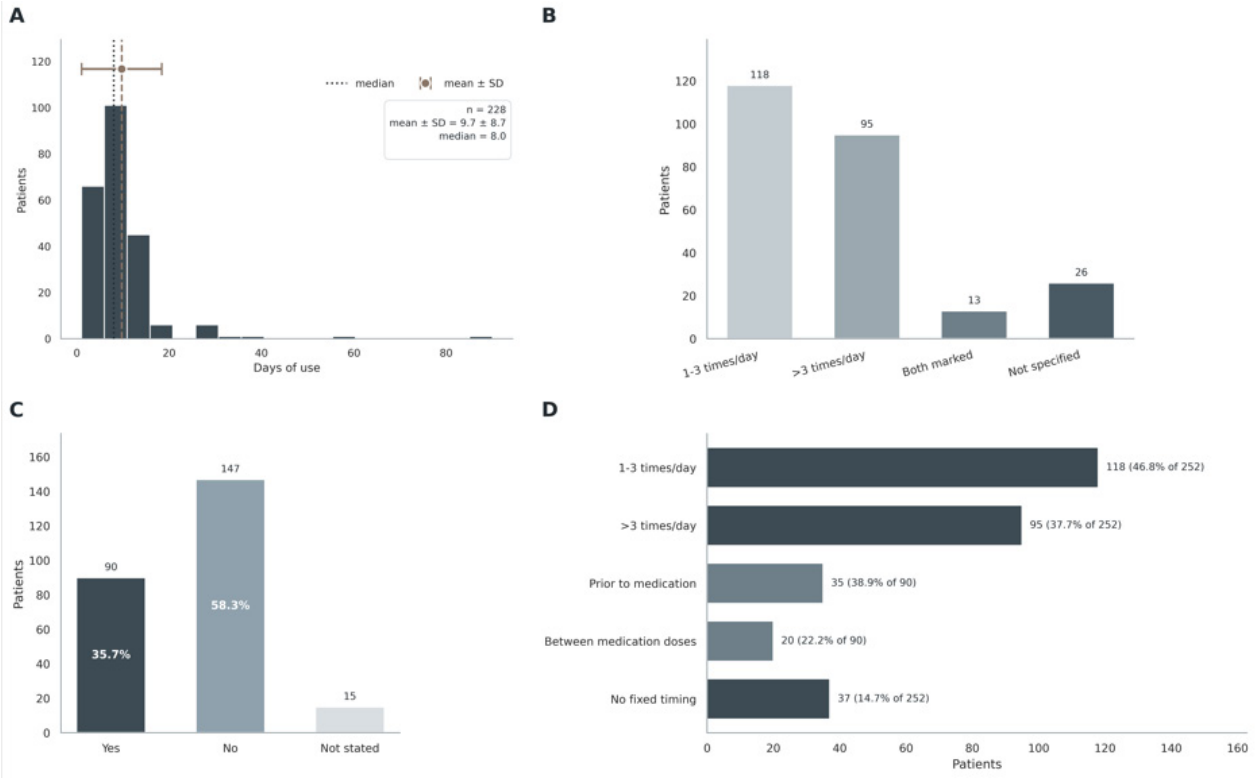


Figure 3. Product use. (A) Duration of use (n = 228); the dotted line indicates the median, and the marker and bar show the mean ± SD. (B) Daily frequency of use in the overall population (n = 252); "both marked" refers to participants who selected both mutually exclusive options. (C) Use of concomitant medicated nasal products (n = 252). (D) Pattern of use, showing frequency of administration in the overall population and timing of administration relative to medication among participants using concomitant medication (n = 90). Participants who selected both frequency options are not shown in the frequency analysis. "No fixed timing" is shown for the overall study population.



Sinonasal and Quality-of-Life Symptom Improvement

HSHD is indicated principally for hydration of the dry nasal mucosa, and the product's performance was therefore first evaluated on the dry/itchy nose domain in participants who reported nasal dryness as an indication for use and had paired dry/itchy-nose scores available (n = 60), compared with participants reporting other indications with paired scores available (n = 131). Participants using the product for dry nose had higher baseline dry/itchy nose scores than those using it for other indications (3.57 vs 3.02; p = 0.032) and a greater reduction in scores after use (2.35 vs 1.76 points; p = 0.030) (**Figure 4A**). However, the difference in baseline scores (0.55 points) was similar to the difference in score reductions (0.59 points), and post-use scores were nearly identical between the groups (1.22 vs 1.26). The mean individual relative reduction did not differ significantly (63.3% vs 52.4%; p = 0.35; **Figure 4B**). The greater reduction in the dry-nose group is therefore likely to reflect higher baseline symptom severity rather than a greater effect of the device.

As the product was used for several indications, all ten domains were also assessed in the overall population, rather than only in participants with nasal dryness (**Figure 5A, Table 1**). Scores decreased significantly in all domains (p < 0.001), with mean reductions ranging from 1.39 to 2.31 points and relative reductions from 52.4% to 66.6%. The largest absolute reductions were observed for poor sleep quality (2.31 points, 65.4%) and stuffy nose (2.10 points, 52.8%), while the smallest absolute reductions were for other nasal problems (1.39 points, 52.4%) and emotional state (1.41 points, 63.1%). Relative reductions were larger in domains related to the impact of nasal symptoms, including sleep, overall feeling, productivity, fatigue and emotional state (63.1%–66.6%), compared with 52.4%–60.8% across the nasal symptom domains. The changes were also reflected in the score distributions (Figure 5A). Median scores decreased by two to three points across all ten domains, with post-use medians of 0 or 1 in nine domains. These findings indicate that the observed improvements extended across the study population, rather than being limited to participants with the highest baseline scores. In the 160 participants with all ten domains recorded at both time points, the CTSS decreased from 30.2 ± 13.6 to 11.9 ± 9.6, a mean reduction of 18.3 points (60.5%; p < 0.001), and 151 participants (94.4%) showed a reduction (**Figure 5B**).

Figure 4. Dry/itchy nose domain improvement. (A) Baseline scores and absolute reductions among participants reporting nasal dryness (n = 60) and those reporting other indications only (n = 131). (B) Mean individual relative reduction in the same two groups. p-values were calculated using the Mann–Whitney U test.

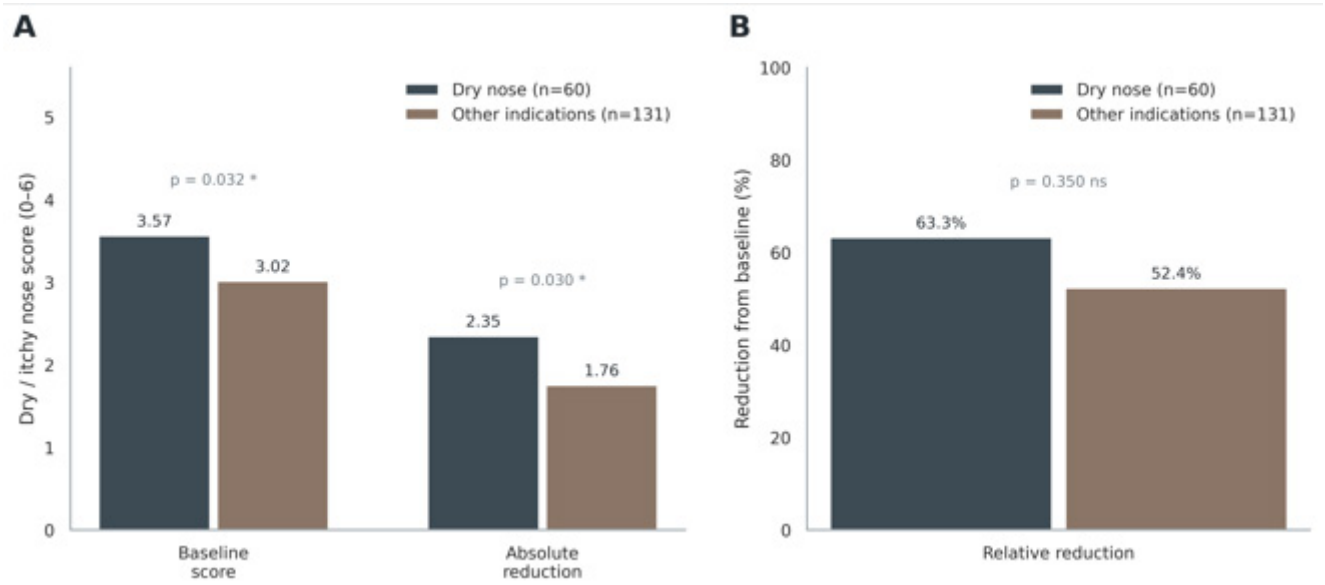


Figure 5. Symptom scores before and after product use. (A) Scores across the ten symptom domains before and after product use (0 = not troubled, 6 = extremely troubled); n is shown above each plot. (B) Composite Total Symptom Score (CTSS; range, 0–60) in participants with all ten domains recorded at both time points (n = 160). p-values were calculated using the Wilcoxon signed-rank test. Boxes show the median and interquartile range, whiskers show 1.5 × the interquartile range, and points represent individual participants.

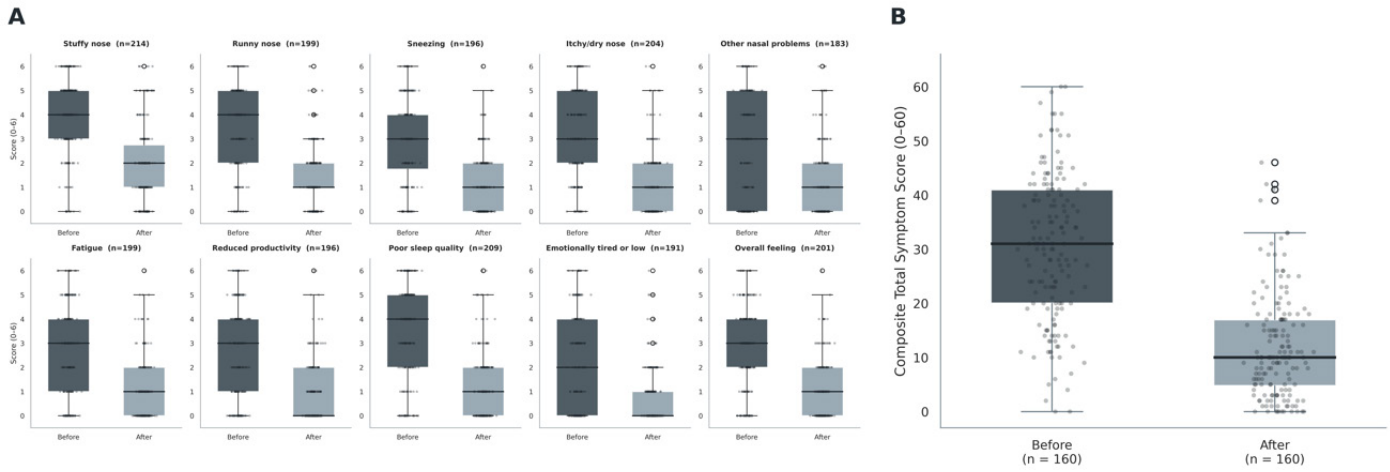


Table 1. Symptom scores before and after use of HSHD, total population. Scores are on a 0–6 scale (0 = not troubled, 6 = extremely troubled) and are given as mean ± SD.

Symptom domain	Before	After	Mean change	Reduction (%)	Improved (%)	n
Stuffy nose	3.97 ± 1.57	1.87 ± 1.54	2.10	52.8	79.4	214
Runny nose	3.39 ± 1.67	1.55 ± 1.31	1.84	54.2	73.9	199
Sneezing	2.95 ± 1.78	1.24 ± 1.19	1.70	57.8	74.5	196
Itchy/dry nose	3.18 ± 1.77	1.25 ± 1.30	1.93	60.8	77.0	204
Other nasal problems	2.66 ± 2.11	1.27 ± 1.52	1.39	52.4	56.3	183
Fatigue	2.80 ± 1.86	1.02 ± 1.25	1.78	63.6	72.4	199
Reduced productivity	2.67 ± 1.93	0.91 ± 1.24	1.76	65.8	70.9	196
Poor sleep quality	3.53 ± 1.85	1.22 ± 1.39	2.31	65.4	82.3	209
Emotionally tired or low	2.23 ± 2.01	0.82 ± 1.21	1.41	63.1	56.5	191
Overall feeling	2.92 ± 1.72	0.98 ± 1.19	1.94	66.6	77.6	201

Reported Onset of Symptom Relief

Among the 239 participants who reported the onset of symptom relief after HSHD use, 72 (30.1%) noticed improvement within 5 minutes and 117 (49.0%) within 30 minutes. In total, 189 participants (79.1%) reported relief within 30 minutes, while 43 (18.0%) reported improvement after more than 30 minutes and 7 (2.9%) reported no improvement (**Figure 6A**).

The day of first improvement was reported by 237 participants. Improvement was first noticed on day 1 by 109 participants (46.0%), rising to 73.0% by day 2 and 92.8% by day 3. The cumulative proportion reached 94.5% by day 5 and 96.2% by day 7. Four participants (1.7%) first reported improvement after day 5, and another four (1.7%) after day 7; 9 (3.8%) reported no improvement (**Figures 6B, 6C**).

Reported Medication Reduction and Standalone Use

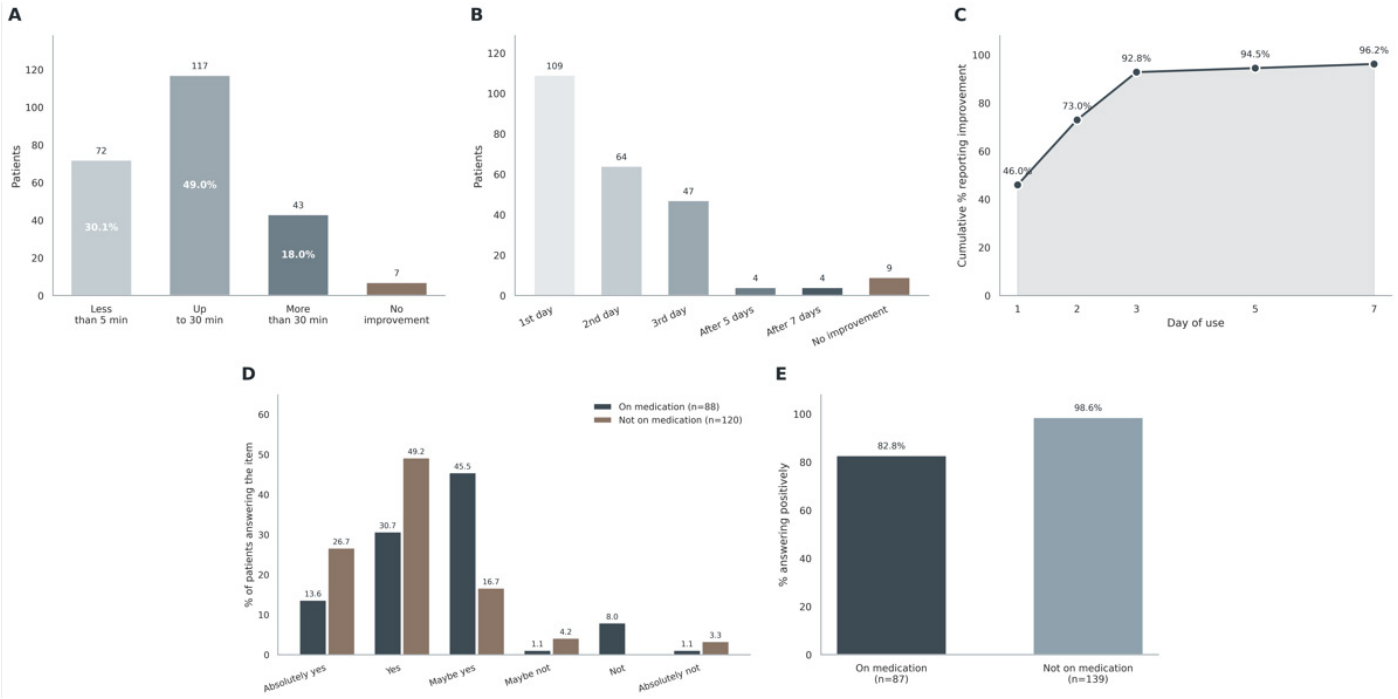
The potential for HSHD use to reduce the use of medicated nasal products was assessed based on participant-reported changes in medication intake and willingness to use HSHD without concomitant medication.

Among the 210 participants who responded regarding medication intake, 192 (91.4%) gave a positive response regarding a perceived reduction in their overall use of medicated nasal products, including 21.0% who responded “Absolutely yes”, 41.9% “Yes” and 28.6% “Maybe yes”. Of these 210 respondents, 88 were using concomitant medicated nasal products, 120 were not, and 2 did not state their medication status. The proportion reporting a reduction was similar in the two groups (79/88, 89.8% and 111/120, 92.5%), although the question is directly applicable only to participants who were using concomitant medication (**Figure 6D**).

Among the 228 participants who responded regarding use without medication, 211 (92.5%) reported that they would consider

using HSHD alone. Of the 228 respondents, 87 were using concomitant medicated nasal products, 139 were not, and 2 did not state their medication status. The proportion was lower among participants using concomitant medication (72/87, 82.8%) than among those not using concomitant medication (137/139, 98.6%), consistent with the question implying replacement of an existing treatment in the first group and being largely hypothetical in the second (**Figure 6E**).

Figure 6. Onset of symptom relief and medication-related outcomes. (A) Time to symptom relief after a single administration (n = 239). (B) Day on which improvement was first noticed (n = 237). (C) Cumulative proportion of participants reporting improvement by each day of use (n = 237). (D) Reported reduction in overall medicated-product intake among participants using and not using concomitant medication (n = 88 and n = 120, respectively). (E) Willingness to use the product without medication among participants using and not using concomitant medication (n = 87 and n = 139, respectively); Fisher's exact test, $p < 0.001$.



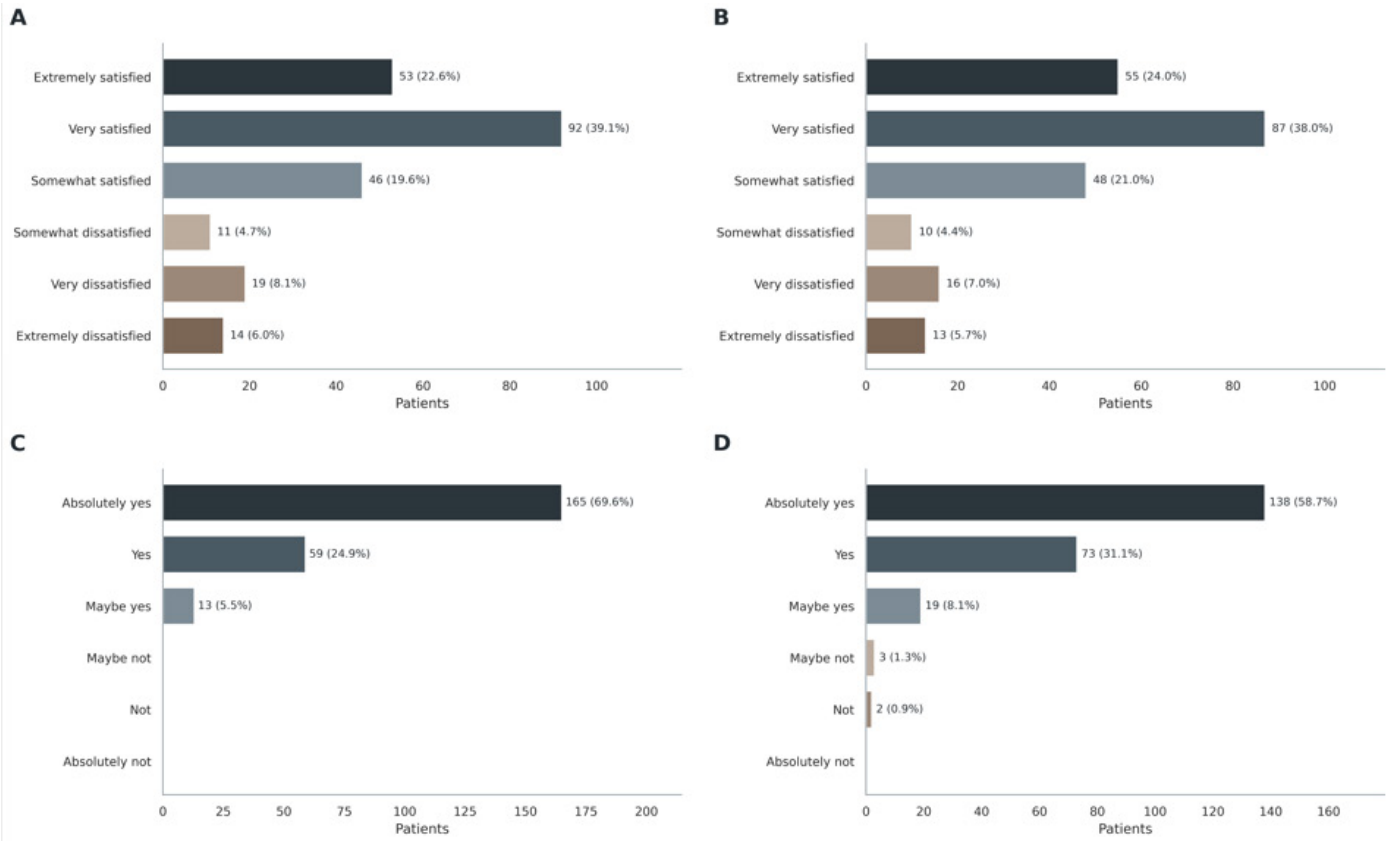
User Satisfaction and Ease of Use

Overall satisfaction, perceived efficacy, ease of use and willingness to recommend or repurchase were also assessed (Figure 7). Among the 235 participants who responded to the overall satisfaction item, 53 (22.6%) were extremely satisfied, 92 (39.1%) very satisfied and 46 (19.6%) somewhat satisfied, corresponding to 191 (81.3%; exact 95% CI, 75.7–86.1%) reporting some degree of satisfaction. Eleven participants (4.7%) were somewhat dissatisfied, 19 (8.1%) very dissatisfied and 14 (6.0%) extremely dissatisfied (**Figure 7A**).

For perceived efficacy, 55 of 229 participants (24.0%) were extremely satisfied, 87 (38.0%) very satisfied and 48 (21.0%) somewhat satisfied, giving 190 (83.0%; exact 95% CI, 77.5–87.6%) positive responses. Negative responses were reported by 10 (4.4%), 16 (7.0%) and 13 (5.7%) participants, respectively (**Figure 7B**).

All 237 participants who responded to the usability item reported that the device was easy to use and understand. Of these, 165 (69.6%) responded "Absolutely yes," 59 (24.9%) "Yes" and 13 (5.5%) "Maybe yes" (**Figure 7C**). Among 235 participants responding to the recommendation or repurchase item, 230 gave a positive response, including 138 (58.7%) "Absolutely yes," 73 (31.1%) "Yes" and 19 (8.1%) "Maybe yes." Three participants (1.3%) responded "Maybe not" and two (0.9%) "Not" (**Figure 7D**).

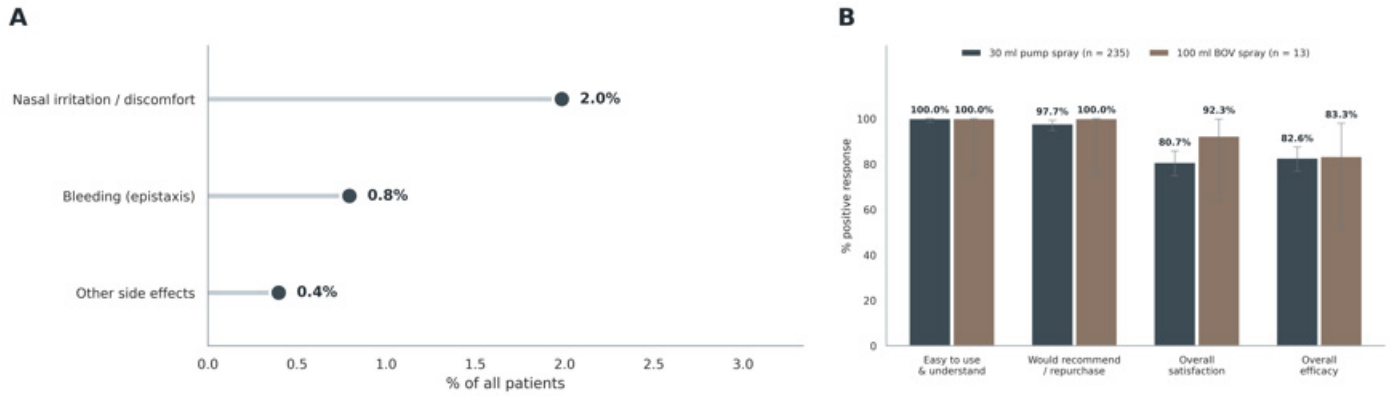
Figure 7. User acceptance. (A) Overall satisfaction (n = 235). (B) Perceived efficacy (n = 229). (C) Ease of use and understanding (n = 237). (D) Willingness to recommend or repurchase (n = 235).



Safety performance

Safety and local tolerability of HSHD were assessed based on participant-reported adverse events during product use. Overall, 8 of 252 participants (3.2%) reported at least one adverse event (**Figure 8A**). Nasal irritation or discomfort was reported by 5 of 239 participants who responded to the corresponding item (2.1%), corresponding to 2.0% of the total study population. Epistaxis was reported by 2 of 229 participants (0.9%), corresponding to 0.8% of the total population (Figure 8A). One of these events was recorded in the pediatric population. One additional participant reported a stinging sensation after use. An additional organoleptic complaint ("the nose spray smells weird") was recorded and classified as a product complaint rather than an adverse event. All reported adverse events were mild and self-resolved. Considering device performance, no device malfunction was reported (0/239).

Figure 8. Safety and device-specific outcomes. (A) Participants reporting adverse events, expressed as a percentage of the total study population (n = 252). (B) Usability and user acceptance according to device format (30 mL pump spray, n = 235; 100 mL BOV spray, n = 13). Error bars represent exact (Clopper–Pearson) 95% confidence intervals; denominators correspond to the number of participants who responded to each item.



Device-variant analysis: 30 mL pump spray and 100 mL BOV spray

Device-specific analyses were performed for the two available delivery formats, the 30 mL pump spray and the 100 mL BOV spray. Of the 248 participants with device format recorded, 235 (94.8%) used the 30 mL pump spray and 13 (5.2%) used the 100 mL BOV spray (Figure 1). Because device format was not randomly assigned, the groups differed in participant characteristics and recruitment, and the BOV group was small. Therefore, symptom outcomes were not analyzed separately by device format.

Table 2. Baseline characteristics by device format.

Characteristic / outcome	30 mL pump spray (n = 235)	100 mL BOV spray (n = 13)	p-value
Age, years, mean ± SD	42.3 ± 15.8	47.1 ± 11.6	0.17
Age range, years	8–88	33–75	–
Female, n/N (%)	144/232 (62.1)	13/13 (100)	0.005
Participants <18 years, n	7	0	–
Baseline CTSS, mean ± SD	29.7 ± 12.9	43.3 ± 15.9	0.007
Use duration, days, mean ± SD	9.8 ± 8.8	8.7 ± 7.9	–

The groups differed in sex and baseline CTSS (**Table 2**). All 13 participants using the 100 mL BOV spray were female, compared with 144/232 (62.1%) using the 30 mL pump spray (Fisher's exact test, p = 0.005). No children were included in the BOV group. Mean age was 47.1 ± 11.6 years in the BOV group and 42.3 ± 15.8 years in the pump-spray group (p = 0.17), while baseline CTSS was higher in the BOV group (43.3 ± 15.9 vs. 29.7 ± 12.9; p = 0.007). In addition, participants using the BOV spray were recruited from only two of the four collection sites. These differences and the small size of the BOV group limit the interpretation of any between-format comparison of symptom outcomes.

Device-specific outcomes were therefore limited to usability, user acceptance, safety and device performance. All participants who responded to the usability item reported that the device was easy to use (220/220 for the 30 mL pump spray and 13/13 for the 100 mL BOV spray). Willingness to recommend or repurchase was reported by 213/218 participants (97.7%) using the 30 mL pump spray and 13/13 (100%) using the BOV spray. Overall satisfaction was reported by 176/218 participants (80.7%) and 12/13 (92.3%), respectively (**Figure 8B**). No adverse events or device malfunctions were reported in the BOV group.

DISCUSSION

This survey set out to describe how a hypertonic seawater spray containing hyaluronic acid and dexpanthenol performs when used under routine conditions of use. The data showed that the use of HSHD was associated with a consistent improvement across all ten assessed domains, and most participants reported relief within 30 minutes of administration and within the first three days of use. Overall HSHD use was accompanied by a low rate of local events and no reported device malfunction.

HSHD was used across a range of indications, which include, apart from nasal dryness, allergic rhinitis, nasal hygiene and moisturization, common cold and influenza, infectious rhinitis, and recovery after endonasal surgery, and more than one indication was reported by 28% of participants. The relative improvement in the dry/itchy nose domain did not differ significantly between participants using HSHD for nasal dryness and those using it for other indications, which is consistent with the proposed mechanism of mucosal hydration restoration and support of mucociliary clearance, a mechanism common to several conditions in which nasal dryness and obstruction arise [1,2,13]. In addition, sleep quality, fatigue, productivity, emotional state and overall feeling improved by 63–67% relative to baseline, matching or exceeding the improvement in the basic nasal symptoms (52.4–60.8%). A similar pattern, with greater relative improvements in quality-of-life domains, was observed in our previous real-world surveys of 2.3% hypertonic seawater sprays used predominantly for the common cold and influenza [18,19], while improvements in sleep and feeding were reported in infants using hypertonic seawater nasal drops [20]. The impact of nasal obstruction on sleep and quality of life is well recognized in rhinitis and rhinosinusitis [3,4,7].

The time course of relief was also comparable to that observed with related seawater formulations. In the present survey, 79.1% of participants reported relief within 30 minutes of administration and 92.8% by the third day of use, compared with 83.9% and 91.9%, respectively, for a herbal-enriched 2.3% hypertonic seawater spray [19], and with 89% and 92% for a formulation enriched with algal and herbal ingredients [18]. The rapid onset is consistent with the immediate osmotic and mechanical effects of hypertonic seawater on the nasal mucosa [12], whereas the further improvement over the first days of use may reflect progressive restoration of mucosal hydration and epithelial integrity, to which sodium hyaluronate and dexpanthenol are expected to contribute [13,14]. Likewise, the adverse event profile is in line with that reported for hypertonic saline preparations [12] and for other seawater-based sprays evaluated under routine conditions

of use [18,19,21]. High user satisfaction and willingness to recommend or repurchase have similarly been reported in these and earlier real-world surveys of seawater-based nasal preparations [18–22].

More than one-third of participants reported concomitant use of medicated nasal products, most commonly topical decongestants, for which mucosal drying and rebound congestion are the principal use-limiting effects [23]. Of participants answering, 91.4% perceived a reduction in their overall medicated-product intake, including 89.8% of those actually using concomitant medication. This is a self-reported perception collected without a control group or any objective measure of consumption, and it cannot support a medication-sparing claim; it does, however, describe a consistent and clinically plausible user experience that warrants formal evaluation in a controlled design with quantified medication use as a pre-specified endpoint. Similar perceptions were reported by concomitant-medication users in our previous surveys [18,19,24]. These observations are consistent with systematic-review evidence that saline irrigation may reduce medication use in allergic rhinitis [11].

The present findings are broadly consistent with previous evidence on the use of saline and seawater-based nasal preparations. Systematic reviews have reported symptomatic benefits of saline treatment in acute upper respiratory tract infections [8] and allergic rhinitis [9,11], including reduced use of concomitant medication in some studies. Nasal irrigation is also widely used as an adjunctive treatment in chronic rhinosinusitis [10].

Evidence has additionally emerged for formulations containing hyaluronic acid and dexpanthenol. In a randomized trial involving patients with nasal dryness, nasal sprays containing hyaluronic acid, either alone or in combination with dexpanthenol, produced greater improvements in dryness-related symptoms than isotonic saline [6]. Similarly, a controlled observational study conducted after septoplasty, ethmoid surgery, and turbinate surgery suggested a trend towards improved mucosal regeneration with a hyaluronic acid–dexpanthenol spray, although the differences compared with standard postoperative care were not statistically significant [5]. Hypertonic seawater irrigation at a concentration of 2.3% has also been evaluated following endoscopic sinus surgery [25]. These findings are of particular relevance to the postoperative use reported by a subset of participants in the present survey.

The current results are also consistent with previously reported real-world survey data on related seawater preparations in ENT populations [18–22]. Nevertheless, direct comparison across studies should be made cautiously, as nasal preparations vary substantially with respect to formulation, tonicity, irrigation volume, delivery system, and frequency of administration, and these methodological and product-related characteristics are not consistently reported [26].

This survey extends the existing literature by evaluating a broad range of indications in a real-world, heterogeneous population and by assessing both nasal and systemic symptom domains within the same survey instrument. This broader assessment may provide additional insight into how such preparations are used and perceived across heterogeneous ENT-related conditions in routine practice.

Study limitations

Several limitations of this study should be acknowledged. First, the single-arm, uncontrolled design precludes causal attribution of the observed symptom improvements to HSHD. All outcomes were based on patient self-report and are therefore subject to reporting and recall bias. Furthermore, the absence of objective clinical assessments, such as nasal endoscopy, microbiological analyses, or validated disease-specific patient-reported outcome measures (e.g., SNOT-22), limits the ability to correlate symptom improvement with objective clinical parameters. In addition, the subgroups were small (100 mL BOV, n = 13; under 18 years, n = 7), so findings for them are descriptive only. Nevertheless, the consistency of improvements observed across multiple symptoms and quality-of-life domains, together with the favorable safety and tolerability profile, supports the real-world utility of HSHD.

CONCLUSION

In this real-world survey of 252 users, use of the seawater-based nasal spray was associated with reductions in all ten assessed nasal and nasal-related symptom domains, with relative reductions ranging from 52% to 67% and a 60.5% reduction in composite symptom burden. Most participants reported symptom relief within 30 minutes, and improvement within the first three days was reported by more than 90% of participants. Adverse events were infrequent, no device malfunctions were reported, and user-reported usability and acceptance were high.

The uncontrolled, prospective before-and-after design does not allow causal effects to be established. In addition, the small number of participants using the 100 mL BOV format and the limited number of pediatric participants preclude separate conclusions for these groups. Within these limitations, the findings provide real-world data on symptom outcomes, tolerability, usability and user acceptance during routine use of the product.

Conflicts of Interest

SG and KA are employees of Gerolymatos-International. SA.

Funding

Not applicable.

Abbreviations

HSHD: Hypertonic Seawater Hyaluronic Dexpanthenol; BOV: Bag-on-valve; CI: Confidence interval; CTSS: Composite Total Symptom Score; PMCF: Post-market clinical follow-up; SNI: Saline nasal irrigation; AE: Adverse Event.

REFERENCES

1. Beule AG. Physiology and pathophysiology of respiratory mucosa of the nose and the paranasal sinuses. GMS Curr Top Otorhinolaryngol Head Neck Surg. 2011;9:Doc07.

2. Bastier PL, Lechot A, Bordenave L, Durand M, de Gabory L. Nasal irrigation: from empiricism to evidence-based medicine. A review. Eur Ann Otorhinolaryngol Head Neck Dis. 2015;132(5):281–285.

3. Fokkens WJ, Lund VJ, Hopkins C, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. Rhinology. 2020;58(Suppl S29):1–464.

4. Bousquet J, Schünemann HJ, Togias A, et al. Next-generation allergic rhinitis and its impact on asthma (ARIA) guidelines for allergic rhinitis based on grading of recommendations assessment, development and evaluation (GRADE) and real-world evidence. J Allergy Clin Immunol. 2020;145(1):70–80.

5. Gouteva I, Shah-Hosseini K, Meiser P. Clinical efficacy of a spray containing hyaluronic acid and dexpanthenol after surgery in the nasal cavity (septoplasty, simple ethmoid sinus surgery, and turbinate surgery). J Allergy (Cairo). 2014;2014:635490. doi:10.1155/2014/635490.

6. Thieme U, Müller K, Bergmann C, Bock B, Wurzer-Materna N, Shahab T, Zeman F, Eberhardt Y, Huppertz G, Koller M, Meiser P. Randomised trial on performance, safety and clinical benefit of hyaluronic acid, hyaluronic acid plus dexpanthenol and isotonic saline nasal sprays in patients suffering from dry nose symptoms. Auris Nasus Larynx. 2020;47(3):425–434.

7. Léger D, Annesi-Maesano I, Carat F, et al. Allergic rhinitis and its consequences on quality of sleep: an unexplored area. Arch Intern Med. 2006;166(16):1744–1748.

8. King D, Mitchell B, Williams CP, Spurling GKP. Saline nasal irrigation for acute upper respiratory tract infections. Cochrane Database Syst Rev. 2015;(4):CD006821.

9. Head K, Snidvongs K, Glew S, et al. Saline irrigation for allergic rhinitis. Cochrane Database Syst Rev. 2018;6:CD012597.

10. Chong LY, Head K, Hopkins C, et al. Saline irrigation for chronic rhinosinusitis. Cochrane Database Syst Rev. 2016;(4):CD011995.

11. Hermelingmeier KE, Weber RK, Hellmich M, Heubach CP, Mösges R. Nasal irrigation as an adjunctive treatment in allergic rhinitis: a systematic review and meta-analysis. Am J Rhinol Allergy. 2012;26(5):e119–e125.

12. Kanjanawasee D, Seresirikachorn K, Chitsuthipakorn W, Snidvongs K. Hypertonic saline versus isotonic saline nasal irrigation: systematic review and meta-analysis. Am J Rhinol Allergy. 2018;32(4):269–279.

13. Pignataro L, Marchisio P, Ibba T, Torretta S. Topically administered hyaluronic acid in the upper airway: A narrative review. Int J Immunopathol Pharmacol. 2018 Jan-Dec;32:2058738418766739. doi: 10.1177/2058738418766739. PMID: 29569499; PMCID: PMC5871036.

14. Mösges R, Shah-Hosseini K, Hucke HP, Joisten MJ. Dexpanthenol: An Overview of its Contribution to Symptom Relief in Acute Rhinitis Treated with Decongestant Nasal Sprays. Adv Ther. 2017 Aug;34(8):1850-1858. doi: 10.1007/s12325-017-0581-0. Epub 2017 Jul 10. PMID: 28695477; PMCID: PMC5565656.

15. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Off J Eur Union. 2017;L117:1–175.

16. Medical Device Coordination Group. MDCG 2020-7: Post-market clinical follow-up (PMCF) plan template; MDCG 2020-8: PMCF evaluation report template. European Commission; 2020.

17. Clopper CJ, Pearson ES. The use of confidence or fiducial limits illustrated in the case of the binomial. Biometrika. 1934;26(4):404–413.

18. Gumeni S, Alevizopoulos K. Hypertonic seawater spray enriched with algal and herbal ingredients in patients with ENT conditions: a real-world user survey. Int J Clin Stud Med Case Rep. 2026;60(4):005. doi:10.46998/IJCMCR.2026.60.001495.

19. Gumeni S, Alevizopoulos K. Herbal-enriched hypertonic seawater spray in sinonasal conditions: a prospective real-world user survey. Int J Clin Stud Med Case Rep.

2026;61(5). doi:10.46998/IJCMCR.2026.61.001521.

20. Gumeni S, Jovanovska A, Micevska V, Gruevska O, Alevizopoulos K. Use of hypertonic seawater nasal drops in infants with ENT symptoms: real-world efficacy, safety and performance evaluation. J Clin Images Med Case Rep. 2026;7(4):4033. doi:10.52768/2766-7820/4033.

21. Gumeni S, Alevizopoulos K. A real-world user survey study conducted with an isotonic seawater nasal spray in patients with ENT disorders. Int J Clin Stud Med Case Rep. 2026;59(5):004. doi:10.46998/IJCMCR.2026.59.001474.

22. Georgiou S, Alevizopoulos K. A real-world user survey study conducted with a hypertonic seawater nasal irrigation solution comprising algal and herbal ingredients in patients with ENT disorders. Int J Clin Stud Med Case Rep. 2021;17(4):002. doi:10.46998/IJCMCR.2021.17.000417.

23. Ramey JT, Bailen E, Lockey RF. Rhinitis medicamentosa. J Investig Allergol Clin Immunol. 2006;16(3):148–155.

24. Georgiou S, Alevizopoulos K. A real-world user survey on the effectiveness of a hypertonic seawater nasal spray as an add-on to pharmacological treatment in patients with ENT diseases. Int J Clin Stud Med Case Rep. 2023;25(4):1–4.

25. Penezić A, Kalogjera L, Grgić MV, Geber G, Tomljenović D, Alevizopoulos K, Baudoin T. Efficacy of nasal irrigation with isotonic and hypertonic solutions after endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis. Acta Clin Croat. 2025;64(1):111–117. doi:10.20471/acc.2025.64.01.12.

26. Principi N, Esposito S. Nasal irrigation: an imprecisely defined medical procedure. Int J Environ Res Public Health. 2017;14(5):516.