

Redundancy of Pharmacologic Ingredients in Over-the-Counter Nasal Sprays

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Abstract

Objective. To evaluate and determine the prevalence of ingredients in over-the-counter (OTC) nasal sprays.

Study Design. Cross-sectional.

Setting. Retail pharmacies.

Methods. An inventory of brand-name and generic OTC nasal sprays was recorded at five national pharmacy outlets in August 2023. Data regarding the active ingredients were collected on commercial websites, MedlinePlus and drugs.com, and frequency statistics were calculated.

Results. Five pharmacies were visited, at which 12 different brand names of nasal sprays were identified at multiple pharmacies. Nine brand names were associated with multiple formulations, accounting for 49 different products. The active ingredients included in our analysis were oxymetazoline, phenylephrine, fluticasone, triamcinolone, budesonide, azelastine, cromolyn sodium, and mometasone. Nasal decongestants had the greatest number of brand name formulations compared to intranasal steroids and antihistamine sprays which had limited choices. Products that included oxymetazoline were the most widely marketed drug (51 unique products) followed sodium chloride (40 unique products).

Conclusion. These findings suggest that there are widespread redundancies in the OTC nasal spray market. Clinician should be aware of the redundancy in OTC formulations and encourage patients to read the labels in order to make informed decisions regarding their use of OTC medications.

Keywords

antihistamine, corticosteroid, decongestant, nasal spray, over-the-counter medications, sinonasal medications

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The realm of over-the-counter (OTC) medications is often perceived to offer products carefully formulated to address specific health concerns. However, beneath these easily accessible and apparently

simple treatments lies an overlooked phenomenon: the unsung redundancies that pervade the OTC drug market. This phenomenon becomes particularly evident when considering the medications marketed for treatment of sinonasal symptoms experienced by millions worldwide.¹ The complexity of these medications is a byproduct of the variety of products available, but also by the number of products containing more than 1 active ingredient.^{2,3}

While OTC sinonasal medications are among one of the most confusing consumer markets, they also account for a large percentage of annual sales in the United States.^{2,4} Numerous nasal sprays are marketed, each claiming superiority over others, creating an environment of consumer choice that often masks the underlying similarities in their active pharmacologic ingredients. These similarities can be either unnecessary for patients, or in worse cases, harmful.

Given the ease of accessibility to OTC medications, consumers may assume that they are benign and harmless.^{5,6} For instance, one study surveyed US consumers and found that up to 41% of consumers believe that OTC medications are too weak to cause any health problems. Furthermore, approximately one-quarter (28%) of participants reported taking 3 or more nonprescription medications per month. The simultaneous use of multiple prescription and nonprescription medications can increase the likelihood of adverse reactions.

This study examines the active ingredients of OTC nasal sprays marketed to US consumers, highlighting the commonalities and differences that exist across various brands and formulations. We aimed to evaluate common brand name and generic products of nasal sprays and their pharmacologic ingredients. Our goal was to

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illuminate the redundancies that persist across this market sector and explore their implications for both consumers and health care practitioners.

Methods

A cross-sectional survey of OTC nasal sprays was performed and analyzed in August 2023. This study did not require Institutional Review Board approval as it did not involve human subject data. An inventory of brand names of OTC nasal sprays was recorded at retail outlets of 5 major national pharmacy chains in New Orleans and Metairie, Louisiana. Retailer generic formulations (eg, Walgreens or CVS fluticasone) were excluded from our analysis due to the wide variation of generics available and limitations of obtaining this data from our regional cross-sectional study.

A product was defined as a substance used for medical treatment. An ingredient was defined as a specific pharmaceutical molecule and a formulation was defined as a mixture of 2 or more ingredients. Brand-name OTC nasal sprays products and their main active ingredients were documented. Products administered by mouth to treat sinonasal symptoms and nonbrand-name products (including store-branded products) were excluded.

The list of common brand names obtained from the pharmacy visits was used to search the proprietary websites of each individual product, tabulating the number of formulations available under each specific brand name. The list of generic names from the pharmacy visits were used to search the Drugs, Herbs, and Supplements section of the United States National Library of Medicine website (www.MedlinePlus.gov) for a listing of all brand-name uses of that ingredient and the different number of formulations.⁷ The names and prevalence of the various formulations were obtained through online query of a centralized reference website (www.drugs.com).⁸

Results

Fifteen different brand names of nasal sprays were found at 5 pharmacies visited. Twelve of these were identified at multiple pharmacies and were included in our analysis. Evaluation of the 12 unique products using the proprietary drug company's websites demonstrated that 9 of the brand names of nasal sprays were associated with multiple formulations. This accounted for a total of 49 different products (**Table 1**).

The brand names with the greatest number of unique products were NeilMed (NeilMed Pharmaceuticals Inc), Afrin (Bayer), Ayr (B.F. Ascher & Co, Inc), and Flonase (GSK Consumer Healthcare) which have for 14, 10, 6, and 4 unique products, respectively.

To evaluate for the number of brand name products that are available for a given generic product, the generic names of products were queried on www.drugs.com. Our analysis demonstrated that the majority of nasal sprays contained only 1 active ingredient. Additionally, there were numerous redundancies in number of products on the market for the same drug. We identified 9 common active ingredients in the nasal sprays: oxymetazoline, sodium chloride, phenylephrine, fluticasone, triamcinolone, budesonide, azelastine, cromolyn sodium, and mometasone.

Of these 9 ingredients, there were 132 unique brand-name products (**Table 2**). Oxymetazoline alone is marketed as 51 different products. Within the Afrin brand, there are at least 10 different Afrin products such as Afrin All Night No Drip, Afrin Allergy Sinus, Afrin Extra Moisturizing, and Afrin Severe Congestion. The active ingredient among the Afrin products were consistently 0.05% oxymetazoline hydrochloride and there were minor differences between the inactive ingredients. Another common decongestant, phenylephrine, was also found to have 15 unique brand name products. Aside from sodium chloride, other nasal sprays such as those including steroids comprised of less than 10 different brand name products.

Table 1. Brand Names of Common Over-the-Counter Nasal Sprays^a

Brand name	Manufacturer	No. of different products under a brand name	Main/active ingredient
NeilMed	NeilMed Pharmaceuticals Inc	14	Sodium chloride
Afrin	Bayer	10	Oxymetazoline
Ayr	B.F. Ascher & Co, Inc	6	Sodium chloride
Flonase	GSK Consumer Healthcare	4	Fluticasone
Neo-Synephrine	B.F. Ascher & Company Inc	3	Phenylephrine
Vicks Sinex	Proctor and Gamble	3	Oxymetazoline
Mucinex	Reckitt Benckiser Group	2	Oxymetazoline
Nasonex	Merck	2	Mometasone
Zicam	Church & Dwight Co, Inc	2	Oxymetazoline
NasalCrom	Prestige Consumer Healthcare	1	Cromolyn sodium
Nasacort	Sanofi	1	Triamcinolone
Rhinocort	Johnson & Johnson	1	Budesonide
Total		49	

^aData are from proprietary product web pages.

Table 2. Number of Brand Name Products Based on Generic Ingredients of Over-the-Counter Nasal Sprays

Generic name	No. of different brand-name products	Examples
Oxymetazoline	51	Afrin, Sinex, Mucinex
Sodium chloride	40	NeilMed
Phenylephrine	15	Neo-Synephrine
Fluticasone	8	Flonase
Triamcinolone	6	Nasacort
Budesonide	4	Rhinocort
Azelastine	4	Astelin
Cromolyn sodium	2	Nasal crom
Mometasone	2	Nasonex
Total	132	

Data are from ref.⁸ (<https://www.drugs.com>).

Discussion

Our study analyzed 12 most common OTC nasal sprays and found that these 12 products comprised of 49 different products. The brands with the largest number of products were NeilMed, Afrin, Ayr, and Flonase. We identified 9 common active ingredients in the nasal sprays: oxymetazoline, phenylephrine, fluticasone, triamcinolone, budesonide, azelastine, cromolyn sodium, and mometasone. Nasal decongestants compared to nasal steroids are marketed widely featuring varied branding and created numerous redundancies in number of products on the market for the same drug. For consumers seeking a straightforward solution to resolve a specific symptom, being met with the multitude of available brand name products may be overwhelming and perplexing.^{1,9}

The OTC drug market is saturated with brand extensions, whereby multiple products under different names often share the same ingredients.³ This redundancy extends to nasal sprays and poses a challenge for consumers. For instance, if a patient was instructed to use Afrin, they may be puzzled by the 10 different Afrin products (eg, Afrin Original, Afrin Severe, Afrin Allergy Sinus, Afrin Extra Moisturizing). Further complicating self-management of conditions by patients, the definition and understanding of sinonasal symptoms can be substantially different between patients and clinicians.^{10,11} While patients may be seeking treatment for nasal congestion, articulating the nature of their symptoms and corresponding what they aim to treat with how products are marketed can be challenging. The wording and marketing strategies of OTC products is robust and is another topic that should be further explored.

Our study highlights the widespread nature of certain ingredients in OTC nasal spray products. For example, oxymetazoline was identified in 51 distinct brand name products. Although oxymetazoline is an effective nasal decongestant, it carries the risks of rebound congestion and tachyphylaxis.¹² Afrin is a well-known product containing

oxymetazoline, but there also several other brand name products that include this active ingredient such as Mucinex and Vicks Sinex. This lack of clarity can mislead patients who, perhaps advised against Afrin, may unknowingly use a nasal spray containing oxymetazoline. The widespread use of oxymetazoline in various products underscores its marketing to consumers for the treatment of diverse sinonasal symptoms. Recognizing this phenomenon should prompt both consumers and clinicians to be vigilant regarding the actual ingredients present in OTC nasal sprays.

Previous studies have shown that there are redundancies in oral OTC sinonasal drugs.³ For instance, many oral OTC sinonasal medications consist of multiple active ingredients, with combinations of up to 4 active drug ingredients being common. In contrast, our analysis revealed that OTC nasal sprays predominantly feature one major active ingredient, differing mainly in inactive components rather than a combination of active ingredients.

While self-management of symptoms through OTC sinonasal medications can reduce physician visits for rhinitis and sinusitis, thereby decreasing public expenditures,¹³ one challenge in self-management is navigating the availability of different routes of administration of these drugs. For example, while phenylephrine is available as a nasal spray, it is also sold as an oral medication to treat nasal congestion. However, there is limited data supported the use of oral phenylephrine as a nasal decongestant.^{14,15} Notably, the Food and Drug Administration recently concluded that oral phenylephrine is not effective as a nasal decongestant, which will likely lead to removal from OTC medications. This finding was not the same for nasal phenylephrine. At the time of this study, there were over 250 brand-name products containing oral phenylephrine. While patients may benefit from other ingredients in a multi-ingredient formulation, the overlap of ingredients with different application routes may pose harm to patients who are managing sinonasal symptoms with multiple products.

Consumers may be unaware of the active ingredients in OTC medications and their usage or safety information. One study showed that while the vast majority (95%) of Americans read some portion of labels on a nonprescription medication before buying and taking the medication the first time, roughly one-third (34%) read the label for the active ingredient and one-fifth (21%) read the safety information.⁶ As the selection and use of OTC medications continue to increase, it is imperative that patients are educated on the appropriate consumption of OTC medications.

Accurate information about nonprescription drug use is critical when considering escalation of medical management or surgical options. Physicians can play a crucial role in helping patients navigate the complex array of OTC nasal sprays by providing clear guidance on the active ingredients and their intended uses. Given the redundancies and varying formulations available, clinicians should

educate patients on how to read and understand product labels, emphasizing the importance of the active ingredients rather than the brand name. Additionally, physicians can offer recommendations based on individual patient needs, thereby minimizing the risk of misuse or overuse of these products. This proactive approach can ensure safer and more effective use of OTC nasal sprays. Furthermore, patients should be encouraged to bring their medications to health care visits, allowing accurate interpretation of their medication choices.

This study has several limitations. First, our survey focused on local pharmacies within a specific region of the United States. Although this data incorporates products from large national retailers, the product landscape available to consumers may vary across different regions of the country. However, we attempted to account for this by excluding store-branded products that may not have a wide distribution. Additionally, the dynamic nature of the market introduces a challenge, with new products periodically being introduced and others being discontinued, whereas the cross-sectional design of this study captured data at a single point in time and location.

Lastly, it is important to note that our study exclusively includes brand name products, with the exclusion of generic products offered by retailers. Many retailers provide generic medications at a potentially lower cost which may be more accessible to consumers. However, the comprehensive identification of all non-branded, retailer generic products would have demanded a much broader survey and fell beyond the scope of this study.

Conclusion

This study illustrates the complexity faced by consumers in selecting treatments from available OTC nasal sprays, which are characterized by numerous brand extensions with similar ingredients. Intranasal steroids and antihistamine sprays offer limited choices, often marketed succinctly. In contrast, decongestant sprays are abundantly marketed, boasting diverse branding and labeling that may obscure their fundamental similarity in active ingredients. This study emphasizes the importance of obtaining accurate information from patients, encouraging them to scrutinize labels and for clinicians to remain attentive to the evolving OTC landscape.

Author Contributions


Lily N. Trinh, conception and design, data acquisition, analysis and interpretation, drafting the manuscript, critical revision, final approval, accountable for all aspects; **Diandra K. Smith**, data collection and analysis, drafting the manuscript, final approval, accountable for all aspects; **Edward D. McCoul**, conception and design, data acquisition, analysis and interpretation, drafting the manuscript, critical revision, final approval, accountable for all aspects.


Disclosures

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