

# Assessment of Pharmacologic Ingredients in Common Over-the-Counter Sinonasal Medications

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**IMPORTANCE** Sinonasal remedies are the most frequently purchased category of over-the-counter (OTC) drugs in the United States. A variety of options for relief are available under proprietary names, although the actual number of available options may not be readily appreciated by the consumer or the clinician.

**OBJECTIVE** To determine the prevalence of specific ingredients in OTC sinonasal products.

**DESIGN, SETTING, AND PARTICIPANTS** This cross-sectional study took physical inventory of brand-name and generic OTC drugs marketed as sinus, cold, allergy, or nasal remedies. Retail pharmacies in New Orleans, Louisiana, commercial websites, and the Drugs, Herbs and Supplements section of MedlinePlus and drugs.com were searched. Data were collected and analyzed from July 1 to 31, 2018.

**MAIN OUTCOMES AND MEASURES** Frequency of active ingredients in OTC formulations.

**RESULTS** Five pharmacies were visited to identify 18 brands, for which the commercial websites were then searched. The 14 most common brands represented 211 unique products. Only 8 unique nonanalgesic ingredients were identified among these products, with many products sold under the same brand name and with the same active ingredient. Phenylephrine hydrochloride, dextromethorphan hydrobromide, pseudoephedrine hydrochloride, guaifenesin, chlorpheniramine maleate, brompheniramine maleate, diphenhydramine hydrochloride, and doxylamine succinate were the common active ingredients, with all available OTC sinonasal remedies consisting of 1 or more of these ingredients. The frequency of occurrence of each ingredient ranged from 10 to 261 different products. Combinations of 2, 3, or 4 active ingredients occurred frequently in OTC sinonasal products.

**CONCLUSIONS AND RELEVANCE** These findings suggest that proliferation of brand extension products under a common name is pervasive. Clinicians should be aware of the large array of redundant OTC formulations and lack of specificity when discussing brand-name sinonasal remedies with their patients.

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The public's understanding of pharmaceutical products has long been a subject of concern.<sup>1</sup> A panoply of medications treating a multitude of ailments and the capacity required to make an informed decision can be overwhelming to the otherwise uninformed layperson. This confusion may be especially true for over-the-counter (OTC) sinonasal remedies given that a prior study<sup>2</sup> has found that these products constitute one of the most confusing consumer market segments inside or outside health care. Nonetheless, sinonasal remedies constitute the largest segment of the OTC drug market in the United States, amounting to approximately 20% of all annual sales.<sup>3</sup>

Confusion may exist for several reasons. First, the consumer can be frustrated by the seemingly innumerable options available for what is understood to be a simple ailment.

Second, the product claims may be muddled by the inclusion of multiple agents within a single formulation, each of which is intended to treat a different symptom. Third, the identity and intended use of a particular OTC medication is often obscured by the practice among manufacturers of using a single brand name across an entire line of products intended to treat different symptoms. The common thread among these phenomena is confusion stemming not so much from the public's inherent ignorance but from the lack of clarity—deliberate or indeliberate—provided by the product's labeling and marketing. The application of direct-to-consumer advertising may overwhelm the layperson's already tenuous ability to appreciate these sources of confusion.<sup>4,5</sup>

Clinicians who treat sinonasal disease may underestimate the inventory of purported remedies with which their pa-

tients are confronted. Conversely, despite a vast inventory, the actual limited scope of distinct OTC medication options available for sinonasal relief may be unappreciated by the consumer. The effective communication of treatment options, both past and future, requires awareness by both parties about the actual nature of those products as they are made available to the public. To that end, this study investigates the association between brand-name and generic formulations of common OTC sinonasal remedies. Specific aims include estimating the prevalence of individual active ingredients, the specificity of brand-name products, and the prevalence of specific combinations of OTC sinonasal remedies.

## Methods

This study did not involve patients and therefore was beyond the purview of the institutional review board. A cross-sectional study was performed and analyzed from July 1 to 31, 2018. An inventory of brand names of OTC medications was recorded at retail outlets of national pharmacy chains in New Orleans, Louisiana. Five pharmacies were included in the study, selected to represent 5 of the 6 largest national pharmacy retailers in the United States. A medication was defined as a substance used for medical treatment, and a product was defined as a medication that was manufactured for sale. Product names were recorded from the department that contained medication labeled for cold, sinus, allergy, or nasal treatment. Brand-name OTC products and their ingredients were documented, including multiple-drug combination formulations. Non-brand-name products were not included. An ingredient was defined as a specific pharmaceutical molecule, whereas a formulation was defined as a mixture of 2 or more active or inactive ingredients.

The list of common brand names from pharmacy visits was then used as a framework to query the proprietary websites of each individual product. Public-facing information in these websites was used to tabulate the number of formulations available under each specific brand name. The list of generic drug names was used to cross-reference a search of the Drugs, Herbs, and Supplements section of the United States National Library of Medicine website (MedlinePlus) for a listing of all brand-name uses of that ingredient and the number of formulations.<sup>6</sup> The names and prevalence of multiple-ingredient formulations were obtained through an online query of a centralized reference website (drugs.com).<sup>7</sup> Topical formulations, such as nasal sprays, were not included in this analysis.

## Results

Eighteen brand names for sinonasal products were identified from the pharmacies visited. Fourteen brand names were present in all 5 pharmacies, and their proprietary websites were searched. Those 14 common brand names of sinonasal remedies accounted for 211 unique products (Table 1). Brand names representing fewer than 5 unique products were not in-

### Key Points

**Question** Is there ambiguity regarding pharmacologic ingredients in common over-the-counter sinonasal remedies?

**Findings** In a cross-sectional study of over-the-counter sinonasal medications in US pharmacies, 14 common brand names represented 211 unique products. These products consisted of 1 or more of only 8 active nonanalgesic ingredients; brand-name redundancy is pervasive, and labeling does not distinguish products based on the pharmacologic agent.

**Meaning** This study found that the labeling of over-the-counter sinonasal remedies was nonspecific and ingredients were often redundant, which could interfere with effective communication between patients and clinicians.

cluded in this analysis. The widest range of products occurred with the brands Mucinex (Reckitt Benckiser Group plc; 47 products), Tylenol (Johnson & Johnson; 26 products), and Robitussin (Pfizer Inc; 20 products), each of which had at least 1 active ingredient that was present in all products under that brand name.

All of the common brand-name products included, alone or in combination, 1 of 8 nonanalgesic ingredients: phenylephrine hydrochloride, dextromethorphan hydrobromide, pseudoephedrine hydrochloride, guaifenesin, chlorpheniramine maleate, brompheniramine maleate, diphenhydramine hydrochloride, and doxylamine succinate (Table 2). The product prevalence of these 8 ingredients was assessed in the MedlinePlus search. The most frequently occurring individual ingredients were phenylephrine (261 products), dextromethorphan (218 products), pseudoephedrine (130 products), and guaifenesin (127 products) (Figure). Although commonly appearing as ingredients in OTC formulations, the analgesics acetaminophen, ibuprofen, and naproxen were not considered sinonasal medications and therefore not included in this tabulation.

Combinations consisting of 1 of the 8 sinonasal ingredients, with or without an analgesic ingredient, were tabulated from drugs.com. Redundancy was inescapable in combinations of ingredients within brand-name OTC products (Table 3). Combinations consisting of as many as 4 active drug ingredients were common, with a total of 688 brand-name formulations containing 2 or more active ingredients. The most frequent combinations included guaifenesin-dextromethorphan (172 products), guaifenesin-pseudoephedrine (149 products), guaifenesin-phenylephrine (113 products), and guaifenesin-dextromethorphan-phenylephrine (85 products). Many, if not all, of these combinations appeared under brand names that were likewise applied to other combinations as well as to individual agents.

## Discussion

### Proliferation of Brand Extensions

New products appearing as OTC formulations are predominantly a function of creative marketing and direct-to-consumer advertising rather than the introduction of new

**Table 1. Brand Names That Are Applied to Multiple Over-the-Counter Sinus, Cold, and Allergy Products<sup>a</sup>**

Brand name	Manufacturer	No. of different products bearing this name
Mucinex	Reckitt Benckiser Group plc	47
Tylenol	Johnson & Johnson	26
Robitussin	Pfizer Inc	20
Advil	Pfizer Inc	17
Theraflu	Novartis International AG	15
Benadryl	Johnson & Johnson	13
Sudafed	Johnson & Johnson	13
Vicks NyQuil	Proctor & Gamble Company	12
Aleve	Bayer	11
Claritin	Bayer AG	10
Allegra	Perrigo Company plc	9
Vicks Sinex	Proctor & Gamble Company	7
Zyrtec	Johnson & Johnson	6
Triaminic	Novartis International AG	5

<sup>a</sup> Data are from proprietary product web pages.

active ingredients.<sup>8</sup> Nowhere is this practice more apparent than within the pharmacy aisles that contain the sinus, cold, and allergy remedies, where shelf upon shelf brims with a host of products reiterating the same dozen brand names. Consumers seeking relief for sinonasal symptoms and who lack medical or pharmacologic education may experience confusion, frustration, and anxiety when faced with the task of selecting the optimal remedy for their symptoms. Moreover, the naming redundancy found in these so-called brand extensions can have several downstream effects.

During a clinical encounter, the patient with sinonasal symptoms may relate the use of an OTC remedy, invariably referring to the drug by a brand name. The patient assumes that there is specificity to the naming of drugs such that a brand name refers to one and only one generic ingredient. The patient may be aware that one-to-one specificity is the rule among prescription-only medications, and so this assumption is reasonable. Unfortunately for both patients and clinicians, there is no such specificity among OTC sinonasal remedies because several different active ingredients or combinations of ingredients may be marketed under a single common brand name. These products are often distinguished by subtitles that hint at the active ingredient, although the actual drug names appear less prominently on the labeling. This ambiguity precludes the accurate communication of the drug being used to a clinician. According to individual proprietary websites, proliferation of products under a single brand name is the rule; for instance, the brand name Mucinex appears on 47 different products (Table 1). In addition, certain brand names that are more commonly understood as analgesics, including Advil (marketed by Pfizer Inc) and Tylenol, now appear on products containing other ingredients intended to relieve sinonasal symptoms.

As prolific as the OTC options may be under a particular brand name, even more numerous are the different formulations in which a particular active drug ingredient may appear. Individual product names that include several of the most com-

mon active agents may number in the dozens: chlorpheniramine appears in 86, guaifenesin appears in 127, and oral phenylephrine appears in 261 products.<sup>6</sup> It is notable that all single and combination OTC sinonasal remedies are derived from a list of only 8 different active ingredients (Table 2). This fact again reveals the lack of innovation that exists among current OTC sinonasal remedies despite the increasing market presence of those products.

### Proliferation of Combination Drug Formulations

A peculiar trait of OTC sinus and allergy medications is the routine inclusion of multiple pharmacologic agents within a single formulation. It has been reported that more than three-quarters of all such products are combinations with more than 1 active ingredient.<sup>2</sup> This inclusiveness gives tacit approval to a nonspecific approach to self-treatment, which poses several potential problems. First, this arrangement defies the principle of parsimony in medical therapy, whereby a patient should be treated with the least number of drugs possible and thereby minimize the potential for harm. Second, with an increased number of component drugs, the probability increases that a well-intentioned consumer would fail to notice labeling specifying that 1 of the components is contraindicated due to a coexisting medical condition.<sup>2</sup> Third, patients who are acutely ill often seek relief from multiple remedies, which could lead to duplication of drug use and overdose.<sup>2</sup> For instance, an individual may take additional analgesics along with a combination sinus remedy that already contains an analgesic, resulting in potential toxic effects. Adverse effects may be compounded if that individual has coexisting liver or kidney disease.

Confusion among consumers may arise as a result of polypharmacy in the available OTC remedies. A survey of OTC sinus, cold, and allergy medications showed that 36% of these products had 2 active ingredients, 30% had 3 active ingredients, and 11% had 4 active ingredients.<sup>2</sup> Only 23% of OTC sinus, cold, and allergy products contained a single ingredient.<sup>2</sup> Price and convenience probably make these attractive choices for consumers. However, the active ingredients may occur in numerous brand name packages; when generic and off-label packaged products are considered, the number of options is potentially even higher. The seemingly endless available combinations with few meaningful distinguishing features encourages a trial-and-error approach to product selection that is likely to be inefficient if not fruitless.

A formulation that contains more than 1 active ingredient has an increased likelihood of containing a superfluous ingredient. In the best case, this incurs an unnecessary incremental expense; in the worst case, it results in harmful adverse effects or drug interactions. Certain traditionally used OTC remedies may not actually be efficacious when subjected to critical appraisal. For instance, a recent review found insufficient published evidence to justify the use of OTC mucolytics or antitussives.<sup>8</sup>

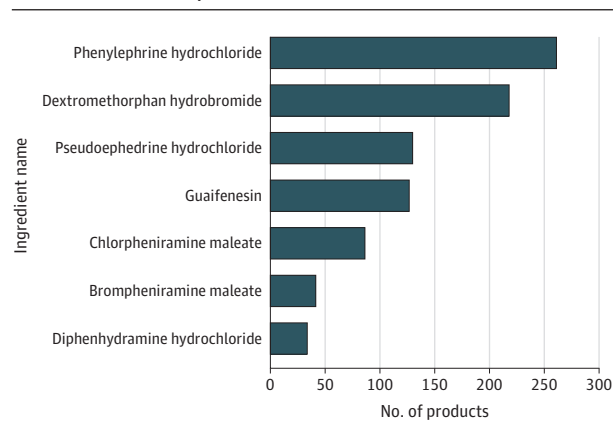
Furthermore, as noted previously with regard to single agents, combinations of drugs may be marketed under many different brand names (Table 3). For example, the combination of acetaminophen, diphenhydramine, and phenyleph-

**Table 2. Generic Over-the-Counter Sinus, Cold, and Allergy Drugs Marketed Under Multiple Brand Names in the United States<sup>a</sup>**

Generic name	No. of different brand-name formulations	Selected brand names	
		Single agent	Combination agents
Phenylephrine hydrochloride (oral)	261	Sudafed PE	Advil Congestion Relief, Alka-Seltzer Plus Cold & Cough Formula, Benadryl-D Allergy Plus Sinus, Children's Dimetapp Cold and Allergy, Robitussin Cough & Cold, Sudafed PE Cold & Cough, Theraflu Cold & Cough, Tylenol Allergy Multi-Symptom
Dextromethorphan hydrobromide	218	Robitussin, Vicks DayQuil Cough & Congestion, Zicam Cough MAX	Alka-Seltzer Plus Cold & Cough Formula, Mucinex DM, Robitussin Cough Plus Chest DM, Sudafed PE Cold & Cough, Triaminic Cough & Sore Throat, Tylenol Cold & Cough Daytime
Pseudoephedrine hydrochloride	130	Sudafed	Advil Allergy Sinus, Aleve-D Sinus & Cold, Allegra-D, Clarinex-D, Claritin-D, Mucinex-D, Sudafed 12 Hour Pressure Plus Pain, Theraflu Max-D Severe Cold & Flu, Tylenol Sinus Severe Congestion Daytime, Zyrtec-D
Guaifenesin	127	Equate, Tussin, Mucinex, Robitussin	Cheratussin AC, Equate Tussin DM, Guaiatussin AC, Mucinex Fast-Max, Robafen DM Max, Robitussin Cough, ChestVicks, Zicam
Chlorpheniramine maleate	86	Chlor-Trimeton	Actifed Cold & Allergy, Alka-Seltzer Plus, Allerest Maximum Strength, Coricidin, Omnihist, Sinarest, Sudafed, Theraflu, Triaminic
Brompheniramine maleate	42	Ala-Hist, Dimetane	Bromfed, Children's Dimetapp, LoHist
Diphenhydramine hydrochloride	34	Benadryl, Sominex, Unisom	Advil PM, Aleve PM, Bayer PM, Benadryl-D Allergy Plus Sinus, Excedrin PM, Goody's PM, Midol PM, Motrin PM, Robitussin Night Time Cough & Cold, Sudafed PE Severe Cold, Theraflu Nighttime Severe Cold and Cough, Triaminic Night Time Cold & Cough, Tylenol Severe Allergy, Unisom With Pain Relief
Doxylamine succinate	10	Aldex, Unisom	Alka-Seltzer Plus, Coricidin, Tylenol Cold & Cough, Vicks NyQuil, Zicam Multisymptom Cold and Flu

<sup>a</sup> Data are from the US National Library of Medicine.<sup>6</sup>

**Figure. Generic Over-the-Counter Sinus, Cold, and Allergy Drugs Marketed Under Multiple Brand Names in the United States**



rine occurs in 21 different brand-name products, including Benadryl (Johnson & Johnson), Delsym (Reckitt Benckiser Group plc), Dimetapp (Pfizer Inc), Mucinex, Robitussin, Sudafed (Johnson & Johnson), and Theraflu (Novartis International AG).<sup>7</sup> All of these brand names also appear on products with other combinations of drugs, underscoring the futility of a patient trying to convey to a clinician the identity of their chosen sinonasal remedy using only a brand name.

**Layperson Perception of Disease**

The quest for relief of sinonasal symptoms is uniquely complicated by matters of semantics. Most people with gastritis

will accurately describe their symptom as a stomach ache or abdominal pain, and most people who have sprained an ankle will describe their symptom as pain in the ankle.<sup>9</sup> In contrast, the layperson's perception of sinonasal anatomy is remarkably fuzzy. The individual with a stuffy nose often claims that their sinuses are blocked, facial pain is attributed to allergies, and clogged ears are indicative of a cold. Even the symptoms may lack a uniform meaning: *congestion* is alternatively described by the layperson as nasal blockage, facial pressure, post-nasal drip, throat clearing, and phlegm in the chest.<sup>10</sup> Moreover, these perceptions may differ substantially between patients and clinicians.

It has long been recognized that physicians and the lay public carry differing interpretations of medical terminology.<sup>9</sup> In the absence of a layperson consensus on linguistics, the perception of sinonasal disease has remained inconsistent and unpredictable. Individuals who believe that an itchy, stuffy nose is due to "sinus" will be motivated to seek out a remedy that is purported to give sinus relief. Interchangeability of the terms *nasal*, *sinus*, and *allergy* in common parlance has the potential to create confusion and muddled expectations among consumers. When these individuals present to a clinician or visit the aisles of a pharmacy, it is plausible—if not probable—that the treatment they receive may not optimally correspond to the symptoms that they seek to relieve.

**Implications for Practice**

Neither clinicians nor patients are likely to have been educated in the full scope of options available on the pharmacy

**Table 3. Combinations of Over-the-Counter Sinus, Cold, and Allergy Drugs Marketed Under Multiple Brand Names<sup>a</sup>**

Agents that compose each formulation	No. of different brand-name products in the United States	Selected brand names
Guaifenesin, dextromethorphan hydrobromide	172	Coricidin, DayQuil, Mucinex, Robitussin, Humibid, Triaminic
Guaifenesin, pseudoephedrine hydrochloride	149	Mucinex, Robitussin, Sudafed, Triaminic, Humibid
Guaifenesin, phenylephrine hydrochloride	113	Sudafed, Triaminic, Nariz, Robitussin
Guaifenesin, dextromethorphan, phenylephrine	85	Mucinex, Robitussin
Acetaminophen, chlorpheniramine maleate, dextromethorphan, pseudoephedrine	30	Alka-Seltzer, Robitussin, Theraflu, Triaminic, Tylenol, Vicks
Acetaminophen, dextromethorphan, guaifenesin, phenylephrine	27	Mucinex, DayQuil, Tylenol, Sudafed
Acetaminophen, diphenhydramine hydrochloride	27	Coricidin, Excedrin, Tylenol
Acetaminophen, phenylephrine	25	Alka-Seltzer, Excedrin, Robitussin, Theraflu, Sudafed, Tylenol, Vicks Sinex
Acetaminophen, diphenhydramine, phenylephrine	21	Benadryl, Delsym, Mucinex, Robitussin, Sudafed, Theraflu, Dimetapp
Acetaminophen, doxylamine succinate, dextromethorphan, pseudoephedrine	14	NyQuil, Tylenol, Robitussin, Alka-Seltzer, Theraflu
Acetaminophen, dextromethorphan, guaifenesin, pseudoephedrine	12	Robitussin, Theraflu, Sudafed, Tylenol
Naproxen sodium, pseudoephedrine	9	Aleve, Sudafed
Acetaminophen, guaifenesin	4	Theraflu, Tylenol

<sup>a</sup> Data are from <http://www.drugs.com>.<sup>7</sup>

shelves. Year upon year of advertising exposure and presumed familiarity with certain brand names belies the reality that most individuals are unaware that brand names are applied across numerous different products and that active ingredients are highly redundant among products with different names. The uncertainty that arises during medicine reconciliation at the time of a health care encounter offers an unrealized opportunity to improve the quality of care for patients with sinonasal disease.

Clinicians should educate patients to inspect the labeling of OTC sinonasal remedies for redundant ingredients that overlap with medications already in use. When discussing OTC

products, patients should be encouraged to refer to them by the active ingredients rather than the brand name, which may be facilitated by bringing the package to the health care encounter.

Clinicians may poise themselves to advise against combinations of agents with multiple ingredients. Both decongestants and the class of older antihistamines possess an array of undesirable adverse effects that might be avoided while achieving greater efficacy of symptom relief with an alternative agent.<sup>11</sup> Similarly, formulations consisting of more than 2 agents may have a higher likelihood of including a drug that does not specifically address a symptom relevant to the patient or one that duplicates the effect of separate medication that the patient is already taking. In these ways, the morass of available OTC sinonasal remedies may ultimately be counterproductive to patient care.

### Limitations

Potential limitations of this study include the single-investigator cross-sectional design and the possible lack of representativeness in the study sample. Centralized online data sources were used to make the findings as generalizable as possible. The geographic limitation of the pharmacy visits was mitigated by including national retailers rather than local or regional pharmacies. This study does not establish the overall prevalence of any specific ingredient in the OTC market sector because commercial product availability may fluctuate over time as products are added to or withdrawn from the market. Moreover, this study is concerned only with brand-name products and their ingredients. Many retailers package the same ingredients as generic medications, sold alongside the brand-name options. A comprehensive study of all nonbranded OTC sinonasal medications would require a nationwide undertaking beyond the scope of this study and would likely increase the finding of available OTC products by an order of magnitude.

### Conclusions

This cross-sectional study found that 8 nonanalgesic active ingredients account for the formulation of hundreds of brand-name OTC sinonasal products. Ambiguous and redundant brand-name labeling of individual and multiple-drug formulations is a potential source of confusion among patients seeking self-directed relief for sinonasal symptoms. Clinicians should be cognizant of the wide array of OTC formulations and the need for specificity when discussing sinonasal remedies with their patients.

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*Drafting of the manuscript:* McCoul.

*Critical revision of the manuscript for important intellectual content:* McCoul.

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