## INFORMATION for the PHARMACIST

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# Considerations of Claritin-D<sup>®</sup> for Nasal Allergy Symptom Relief

n individuals with allergies, exposure to indoor allergens (ie, pet dander and dust mites) and outdoor allergens (ie, pollen and mold spores) will trigger a range of symptoms that can persist year-round, including itchy and watery eyes; runny nose; sneezing; nasal itching; nasal congestion; and sinus pressure. Allergy symptoms can interfere with daily activities and adversely affect physical and emotional well-being. 1-3

Nasal congestion can be particularly burdensome as blocked nasal passages can restrict airflow through the nose and make breathing difficult. In a survey of American adults with nasal and ocular seasonal allergy symptoms (N = 500), the symptoms that respondents rated as most severe were nasal congestion (46%) and stuffy nose (33%). More than 60% of respondents reported managing their allergy symptoms with an OTC allergy medication.

There are many OTC product options available for allergy symptom relief in numerous formulations including antihistamines, nasal decongestants, and intranasal corticosteroid (INS) sprays.<sup>3,4</sup> As these products provide relief from certain allergy symptoms, consumers may have additional questions regarding their symptoms.<sup>1,4,5</sup> Pharmacists are well-positioned to provide counseling to consumers if requested.

## CONSIDERATIONS IN THE SELECTION OF AN OTC ALLERGY MEDICATION

It is important for pharmacists to be aware of the different FDA approved indications and product specific features of the leading allergy brands available in the pharmacy. To support counseling and product selection, the TABLE provides information regarding the INS sprays Flonase® (fluticasone propionate) and Nasacort® (triamcinolone acetonide), and Claritin-D® tablets, which combine an antihistamine (loratadine) and a nasal decongestant (pseudoephedrine sulfate). 6-10

# Differences in FDA-Approved Indications and Allergy Symptom Relief

INS sprays temporarily relieve symptoms of hay fever or other upper respiratory allergies including nasal congestion, runny nose, sneezing, itchy nose, and certain INS products also relieve itchy, watery eyes. 8-10 Claritin-D® has 8 indications, including the temporary relief of itchy throat and sinus congestion and pressure, which are not addressed by INS sprays. 6-10

The antihistamine in Claritin-D® temporarily relieves common allergy symptoms including runny nose, sneezing, itchy and watery eyes, and itching of the nose and throat.<sup>6,7</sup> The nasal decongestant in Claritin-D® reduces swelling of nasal passages and temporarily restores nasal airflow through

2 OTHER OTC ALLERGY BRANDS <sup>6-10</sup>			
	Claritin-D®	Flonase®a	Nasacort®
Sneezing	1	✓	✓
Itchy eyes	✓	√b	
Watery eyes	✓	√b	
Itching of the throat	1		
Itching of the nose	✓	✓	✓
Runny nose	1	/	✓

TABLE. FDA LABELED INDICATIONS FOR CLARITIN-D® AND

°Refers to Flonase® Allergy Relief and Flonase® Sensimist™ Allergy Relief Products. bFlonase® Sensimist™ Allergy Relief is indicated for itchy, watery eyes for ages 12 years and older.

Flonase® and Nasacort® are trademarks of their respective owners.

the nose. Claritin-D® temporarily relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies and also relieves sinus congestion and pressure due to allergies.<sup>6,7</sup>

#### Fast Relief of Nasal Congestion

Nasal congestion

Sinus congestion and pressure

Important considerations that guide the selection of an OTC allergy medication are product effectiveness and fast-acting therapeutic activity to provide quick relief.<sup>2</sup> INS sprays can provide relief from nasal congestion; however, the onset of therapeutic effect is within approximately 12 hours and they provide maximum relief when used consistently for several days.<sup>1,3,8-11</sup> Because the steroid medication in an INS is solubilized into an aqueous medium, the INS spray may coat nasal passages and provide a feeling, similar to using a saline nasal spray; however, the steroid does not exert a therapeutic effect immediately.<sup>1</sup>

For those with nasal congestion symptoms, Claritin-D<sup>®</sup> is an option that starts working on nasal congestion in as little as 30 minutes.<sup>6,7,12-14</sup>

#### Nasal Airflow Changes With Claritin-D®

In a phase 4, randomized, 4-way crossover study (NCT03443843), Claritin-D® improved nasal airflow compared with Flonase® nasal spray after the first dose.  $^{13,14}$  The study enrolled patients with established seasonal allergic rhinitis and demonstrated response to ragweed pollen; eligible patients had allergy symptoms that included nasal congestion.  $^{13,14}$  To induce allergy symptoms, patients (N = 82) were exposed to standardized

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levels of ragweed pollen within an environmental exposure unit, a validated method that provides a controlled, stable, and reproducible environment.<sup>13-15</sup>

Patients were randomized (1:1:1:1) to receive either a single oral dose of Claritin-D® 12 Hour (loratadine 5 mg/pseudoephedrine 120 mg), a placebo tablet, 2 sprays per nostril of Flonase® nasal spray (50 mcg per spray), or 2 sprays per nostril of a placebo nasal spray. The trial was designed with 4 experimental sequences and the crossover treatment design allowed patients to receive each of the 4 study treatments across 4 treatment visits, separated by 14-day intervals. 13,14

Peak nasal inspiratory flow (PNIF) directly measures nasal airflow through the nose in liters per minute during maximal inspiration. Nasal airflow measurements have been used as an outcome measure in the assessment of INS sprays and cough, cold, and allergy products that contain the nasal decongestant pseudoephedrine. <sup>16-21</sup> The study assessed the average percent change in PNIF from pre-dose to 4 hours after dosing, measured every 30 minutes from 0 to 4 hours. <sup>13,14</sup>

In the analysis of the per-protocol population (N = 77), the average percent change in PNIF from pre-dose to 4 hours after dosing in the Claritin-D® treatment group was 31.3% compared with 14.8% in the Flonase® treatment group and 11.6% in the group receiving placebo tablet. In the study, a single dose of Claritin-D® significantly improved nasal airflow compared with placebo tablet (P < .001). Claritin-D® significantly improved nasal airflow compared with Flonase® nasal spray (P < .001). Based on peak intake after the first dose, Claritin-D® improved nasal airflow 2 times more than Flonase® nasal spray at hour 1 (P < .05). <sup>13,14</sup>

#### ROLE OF THE PHARMACIST

As health care professionals readily accessible to consumers in community settings, pharmacists are a helpful resource for additional education on OTC products. Consumers may ask the pharmacist for an OTC product recommendation for fast relief of their allergy symptoms.

Pharmacists have an opportunity to recommend Claritin-D® based on the 8 labeled indications including sneezing, runny nose, nasal congestion, itchy nose, itchy eyes, watery eyes, itchy throat, and sinus congestion and pressure. 6.7 Pharmacists can also note that Claritin-D® tablets are available in 12-hour and 24-hour formulations and that because it contains the second generation anti-histamine, loratadine, Claritin-D® provides non-drowsy symptom relief. 6.7 For those with allergy symptoms that include nasal congestion, pharmacists can provide additional education that in a clinical trial, Claritin-D® improved nasal airflow 2 times more than the leading allergy spray (fluticasone propionate nasal spray) at hour 1, based on peak intake after the first dose. 13,14

It is also important for pharmacists to be aware of OTC allergy product warnings. Those with heart disease, thyroid disease, high blood pressure, diabetes, trouble urinating due to an enlarged prostate gland, and liver or kidney disease should consult their provider before use of Claritin-D®. Claritin-D® should be stopped in cases of allergic reaction; if symptoms do not improve within 7 days or are accompanied by a fever; or if nervousness, dizziness, or sleeplessness occur.<sup>6,7</sup>

By supporting consumers with additional education regarding OTC allergy relief products, pharmacists can assist with selection of the right product.

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