

# EXHIBIT G

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use FLONASE safely and effectively. See full prescribing information for FLONASE.**

**Initial U.S. Approval: 1994**

-----**RECENT MAJOR CHANGES**-----

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Indications and Usage (1)

01/2015

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-----**INDICATIONS AND USAGE**-----

FLONASE Nasal Spray is a corticosteroid indicated for the management of the nasal symptoms of perennial nonallergic rhinitis in adult and pediatric patients aged 4 years and older. (1)

-----**DOSAGE AND ADMINISTRATION**-----

For intranasal use only. Recommended starting dosages:

- Adults: 2 sprays per nostril once daily (200 mcg per day). (2.1)
- Adolescents and children aged 4 years and older: 1 spray per nostril once daily (100 mcg per day). (2.2)

-----**DOSAGE FORMS AND STRENGTHS**-----

Nasal spray. 50 mcg of fluticasone propionate in each 100-mg spray. (3)

-----**CONTRAINDICATIONS**-----

Hypersensitivity to any ingredient. (4)

-----**WARNINGS AND PRECAUTIONS**-----

- Epistaxis, nasal ulceration, *Candida albicans* infection, nasal septal perforation, and impaired wound healing. Monitor patients periodically for signs of adverse effects on the nasal mucosa. Avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma. (5.1)
- Close monitoring for glaucoma and cataracts is warranted. (5.2)
- Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, and rash) have been reported after administration of FLONASE Nasal Spray. Discontinue FLONASE Nasal Spray if such reactions occur. (5.3)
- Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. (5.4)
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue FLONASE Nasal Spray slowly. (5.5)
- Monitor growth of pediatric patients. (5.7)

-----**ADVERSE REACTIONS**-----

The most common adverse reactions (>3%) are headache, pharyngitis, epistaxis, nasal burning/nasal irritation, nausea/vomiting, asthma symptoms, and cough. (6.1)

**To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

-----**DRUG INTERACTIONS**-----

Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir, ketoconazole): Use not recommended. May increase risk of systemic corticosteroid effects. (7.1)

-----**USE IN SPECIFIC POPULATIONS**-----

Hepatic impairment: Monitor patients for signs of increased drug exposure. (8.6)

**See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.**

**Revised: 10/2011**

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**FULL PRESCRIBING INFORMATION**

**1 INDICATIONS AND USAGE**

FLONASE<sup>®</sup> Nasal Spray is indicated for the management of the nasal symptoms of perennial nonallergic rhinitis in adult and pediatric patients aged 4 years and older.

**2 DOSAGE AND ADMINISTRATION**

using for the first time or after a period of non-use (1 week or more) by shaking the contents well and releasing 6 sprays into the air away from the face. Shake FLONASE Nasal Spray gently before each use.

Patients should use FLONASE Nasal Spray at regular intervals since its effectiveness depends on its regular use. Maximum effect may take several days and individual patients will experience a variable time to onset and different degree of symptom relief.

## 2.1 Adults

The recommended starting dosage in adults is 2 sprays (50 mcg of fluticasone propionate each) in each nostril once daily (total daily dose, 200 mcg). The same total daily dose, 1 spray in each nostril administered twice daily (e.g., 8 a.m. and 8 p.m.) is also effective. After the first few days, patients may be able to reduce their dose to 1 spray in each nostril once daily for maintenance therapy.

Maximum total daily doses should not exceed 2 sprays in each nostril (total dose, 200 mcg/day). There is no evidence that exceeding the recommended dose is more effective.

## 2.2 Adolescents and Children (Aged 4 Years and Older)

The recommended starting dosage in adolescents and children, aged 4 years and older is 1 spray in each nostril once daily (total daily dose, 100 mcg). Patients not adequately responding to 1 spray in each nostril may use 2 sprays in each nostril once daily (total daily dose, 200 mcg). Once adequate control is achieved, the dosage should be decreased to 1 spray in each nostril once daily.

The maximum total daily dosage should not exceed 2 sprays in each nostril (200 mcg/day) There is no evidence that exceeding the recommended dose is more effective.

## 3 DOSAGE FORMS AND STRENGTHS

FLONASE Nasal Spray is a nasal spray suspension. Each 100-mg spray delivers 50 mcg of fluticasone propionate.

## 4 CONTRAINDICATIONS

FLONASE Nasal Spray is contraindicated in patients with hypersensitivity to any of its ingredients [*see Warnings and Precautions (5.3), Description (11)*].

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Local Nasal Effects

#### Epistaxis

In clinical trials of 2 to 26 weeks' duration, epistaxis was observed more frequently in subjects treated with FLONASE Nasal Spray than those who received placebo [*see Adverse Reactions (6.1)*].

#### Nasal Ulceration

Postmarketing cases of nasal ulceration have been reported in patients treated with FLONASE Nasal Spray [*see Adverse Reactions (6.2)*].

#### Candida Infection

In clinical trials with fluticasone propionate administered intranasally, the development of localized infections of the nose and pharynx with *Candida albicans* has occurred. When such an infection develops, it may require treatment with appropriate local therapy and discontinuation of FLONASE Nasal Spray. Patients using FLONASE Nasal Spray over several months or longer should be examined

## Nasal Septal Perforation

Postmarketing cases of nasal septal perforation have been reported in patients treated with FLONASE Nasal Spray [see *Adverse Reactions (6.2)*].

## Impaired Wound Healing

Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal ulcers, nasal surgery, or nasal trauma should avoid using FLONASE Nasal Spray until healing has occurred.

## **5.2 Glaucoma and Cataracts**

Use of intranasal and inhaled corticosteroids may result in the development of glaucoma and/or cataracts. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

## **5.3 Hypersensitivity Reactions including Anaphylaxis**

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, and rash) have been reported after administration of FLONASE Nasal Spray. Discontinue FLONASE Nasal Spray if such reactions occur [see *Contraindications (4)*]. Rarely, immediate hypersensitivity reactions may occur after the administration of FLONASE Nasal Spray.

## **5.4 Immunosuppression**

Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or been properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If a patient is exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If a patient is exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the complete prescribing information for VZIG and IG.) If chickenpox develops, treatment with antiviral agents may be considered.

Intranasal corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract; systemic fungal, bacterial, viral or parasitic infections; or ocular herpes simplex.

## **5.5 Hypercorticism and Adrenal Suppression**

When intranasal corticosteroids are used at higher than recommended dosages or in susceptible individuals at recommended dosages, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, the dosage of FLONASE Nasal Spray should be discontinued slowly consistent with accepted procedures for discontinuing oral corticosteroid therapy.

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. In addition, some patients may experience symptoms of corticosteroid withdrawal (e.g., joint and/or muscular pain, lassitude, depression). Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical corticosteroids should be carefully monitored for acute adrenal insufficiency in response to stress. In patients who have asthma or other clinical conditions requiring long-term systemic corticosteroid treatment, rapid decreases in systemic corticosteroid dosages may cause a severe exacerbation of their symptoms.

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