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Notre Dame Scars Nebraska

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NASAL CONGESTION

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SNEEZING

When you've had it with multi-symptom nasal allergies...



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Multi-symptom
FLONASE[®]
(fluticasone propionate)

NASAL SPRAY, 50 mcg

GlaxoWellcome

FLONASE®
(fluticasone propionate)
Nasal Spray, 50 mcg

BRIEF SUMMARY

For Intranasal Use Only.

The following is a brief summary only; see full prescribing information for complete product information.

CONTRAINDICATIONS: FLONASE Nasal Spray is contraindicated in patients with a hypersensitivity to any of its ingredients.

WARNINGS: The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency; and in addition some patients may experience symptoms of withdrawal, e.g., joint and/or muscular pain, lassitude, and 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 these patients who have adrenal or other clinical conditions requiring long-term systemic corticosteroid treatment, too rapid a decrease in systemic corticosteroids may cause a severe exacerbation of their symptoms.

The concomitant use of intranasal corticosteroids with other inhaled corticosteroids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the hypothalamic-pituitary-adrenal (HPA) axis.

Patients who are on immunosuppressant drugs are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in patients on immunosuppressant doses of corticosteroids. In such patients who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affects 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 exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

PRECAUTIONS:

General: Rarely, immediate hypersensitivity reactions or contact dermatitis may occur after the administration of FLONASE Nasal Spray. Rare instances of wheezing, nasal septum perforation, catarrhs, glaucoma, and increased intraocular pressure have been reported following the intranasal application of corticosteroids, including fluticasone propionate.

Use of excessive doses of corticosteroids may lead to signs or symptoms of hypercorticism, suppression of HPA function, and/or reduction of growth velocity in children or teenagers. Physicians should closely follow the growth of children and adolescents taking corticosteroids, by any route, and weigh the benefits of corticosteroid therapy against the possibility of growth suppression if growth appears slowed.

Although systemic effects have been minimal with recommended doses of FLONASE Nasal Spray, potential risk increases with larger doses. Therefore, larger than recommended doses of FLONASE Nasal Spray should be avoided.

When used at higher than recommended doses, or in rare individuals at recommended doses, 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.

In clinical studies with fluticasone propionate administered intranasally, the development of localized infections of the nose and pharynx with *Candida albicans* has occurred only rarely. When such an infection develops, it may require treatment with appropriate local therapy and discontinuation of treatment with FLONASE Nasal Spray. Patients using FLONASE Nasal Spray over several months or longer should be examined periodically for evidence of *Candida* infection or other signs of adverse effects on the nasal mucosa.

FLONASE Nasal Spray should be used with caution, if at all, in patients with active or quiescent tuberculous infection, untreated local or systemic fungal or bacterial, or systemic viral infections or parasitic infection, or ocular herpes simplex. Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septal ulcers, nasal surgery, or nasal trauma should not use a nasal corticosteroid until healing has occurred.

Information for Patients: Patients being treated with FLONASE Nasal Spray should receive the following information and instructions. This information is intended to aid them in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Patients should be warned to avoid exposure to chickenpox or measles and, if exposed, to consult their physician without delay.

Patients should use FLONASE Nasal Spray at regular intervals as directed since its effectiveness depends on its regular use. A decrease in nasal symptoms may occur as soon as 12 hours after starting therapy with FLONASE Nasal Spray. Results in several clinical trials indicate statistically significant improvement within the first day or two of treatment; however, the full benefit of FLONASE Nasal Spray may not be achieved until treatment has been administered for several days. The patient should not increase the prescribed dosage but should contact the physician if symptoms do not improve or if the condition worsens. For the proper use of the nasal spray and to attain maximum improvement, the patient should read and follow carefully the patient's instructions accompanying the product.

Drug Interactions: In a placebo-controlled, crossover study in eight healthy volunteers, coadministration of a single dose of orally inhaled fluticasone propionate (1000 mcg, 5 times the maximum daily intranasal dose) with multiple doses of ketoconazole (200 mg) to steady state resulted in increased mean fluticasone propionate concentrations, a reduction in plasma cortisol AUC, and no effect on urinary excretion of cortisol. This interaction may be due to an inhibition of the cytochrome P450 3A4 isoenzyme system by ketoconazole, which is also the route of metabolism of fluticasone propionate. No drug interaction studies have been conducted with FLONASE Nasal Spray; however, care should be exercised when fluticasone propionate is administered with long-term ketoconazole and other known cytochrome P450 3A4 inhibitors.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Fluticasone propionate demonstrated no tumorigenic potential in mice at oral doses up to 1000 mcg/kg (approximately 20 times the maximum recommended daily intranasal dose in adults and approximately 10 times the maximum recommended daily intranasal dose in children on a mcg/m² basis) for 78 weeks or in rats at inhalation doses up to 57 mcg/kg (approximately 2 times the maximum recommended daily intranasal dose in adults and approximately equivalent to the maximum recommended daily intranasal dose in children on a mcg/m² basis) for 104 weeks.

Fluticasone propionate did not induce gene mutation in prokaryotic or eukaryotic cells *in vitro*. No significant clastogenic effect was seen in cultured human peripheral lymphocytes in *in vitro* or in the mouse micronucleus test when administered at high doses by the oral or subcutaneous routes. Furthermore, the compound did not delay erythropoiesis in bone marrow.

No evidence of impairment of fertility was observed in reproductive studies conducted in male and female rats at subcutaneous doses up to 50 mcg/kg (approximately 2 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis). Prostate weight was significantly reduced at a subcutaneous dose of 50 mcg/kg.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Subcutaneous studies in the mouse and rat at 45 and 100 mcg/kg, respectively (approximately equivalent to 4 and 8 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis, respectively) revealed fetal toxicity characteristic of potent corticosteroid compounds, including embryonic growth retardation, omphalocele, cleft palate, and retarded cranial ossification.

In the rabbit, fetal weight reduction and cleft palate were observed at a subcutaneous dose of 4 mcg/kg (less than the maximum recommended daily intranasal dose in adults on a mcg/m² basis).

SHAKE GENTLY BEFORE USE.

FLONASE® (fluticasone propionate) Nasal Spray, 50 mcg

However, no teratogenic effects were reported at oral doses up to 300 mcg/kg (approximately 25 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis) of fluticasone propionate to the rabbit. No fluticasone propionate was detected in the plasma in this study consistent with the established low bioavailability following oral administration (see CLINICAL PHARMACOLOGY section of the full prescribing information).

Fluticasone propionate crossed the placenta following oral administration of 100 mcg/kg to rats or 300 mcg/kg to rabbits (approximately 4 and 25 times, respectively, the maximum recommended daily intranasal dose in adults on a mcg/m² basis).

There are no adequate and well-controlled studies in pregnant women. Fluticasone propionate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Experience with oral corticosteroids since their introduction in pharmacologic, as opposed to physiologic, doses suggests that rodents are more prone to teratogenic effects from corticosteroids than humans. In addition, because there is a natural increase in corticosteroid production during pregnancy, most women will require a lower exogenous corticosteroid dose and many will not need corticosteroid treatment during pregnancy.

Nursing Mothers: It is not known whether fluticasone propionate is excreted in human breast milk. When inhaled fluticasone propionate was administered to rats at a subcutaneous dose of 10 mcg/kg (less than the maximum recommended daily intranasal dose in adults on a mcg/m² basis), radioactivity was excreted in the milk. Because other corticosteroids are excreted in human milk, caution should be exercised when FLONASE Nasal Spray is administered to a nursing woman.

Pediatric Use: Five hundred (500) patients aged 4 to 11 years of age and 440 patients aged 12 to 17 years were studied in US clinical trials with fluticasone propionate nasal spray. The safety and effectiveness of FLONASE Nasal Spray in children below 4 years of age have not been established.

Oral and, to a lesser extent, inhaled and intranasal corticosteroids have been shown to have the potential to cause a reduction in growth velocity in children and adolescents with extended use. If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that they are particularly sensitive to this effect of corticosteroids should be considered (see PRECAUTIONS).

Geriatric Use: A limited number of patients above 60 years of age (n=275) have been treated with FLONASE Nasal Spray in US and non-US clinical trials. The number of patients is too small to permit separate analysis of efficacy and safety, the adverse reactions reported in this population were similar to those reported by younger patients.

ADVERSE REACTIONS: In controlled US studies, more than 3300 patients with seasonal allergic, perennial allergic, or perennial nonallergic rhinitis received treatment with inhaled fluticasone propionate. In general, adverse reactions in clinical studies have been primarily associated with irritation of the nasal mucous membranes, and the adverse reactions were reported with approximately the same frequency by patients treated with the vehicle itself. The complaints did not usually interfere with treatment. Less than 2% of patients in clinical trials discontinued because of adverse effects; the rate was similar for vehicle placebo and active comparators.

Systemic corticosteroid side effects were not reported during controlled clinical studies up to 6 months' duration with FLONASE Nasal Spray. If recommended doses are exceeded, however, or if individuals are particularly sensitive, or taking other corticosteroids, symptoms of hypercorticism, e.g., Cushing's syndrome, could occur.

The following incidence of common adverse reactions (≥3%, where incidence in fluticasone propionate-treated subjects exceeded placebo) is based upon seven controlled clinical trials in which 538 patients (57 girls and 109 boys aged 4 to 11 years, 137 female and 234 male adolescents and adults) were treated with FLONASE Nasal Spray 200 mcg once daily over 2 to 4 weeks and two controlled clinical trials in which 245 patients (118 female and 127 male adolescents and adults) were treated with FLONASE Nasal Spray 200 mcg once daily over 6 months. Also included in the table are adverse events from two studies in which 167 children (45 girls and 122 boys aged 4 to 11 years) were treated with FLONASE Nasal Spray 100 mcg once daily for 2 to 4 weeks.

Overall Adverse Experiences With ≥3% Incidence on Fluticasone Propionate in Controlled Clinical Trials With FLONASE Nasal Spray in Patients ≥4 Years With Seasonal or Perennial Allergic Rhinitis

	Vehicle Placebo (n=758) %	FLONASE 100 mcg Once Daily (n=167) %	FLONASE 200 mcg Once Daily (n=732) %
Headache	14.6	6.6	16.1
Pharyngitis	7.2	6.0	7.8
Epistaxis	5.4	6.0	6.9
Nasal burning/ Nasal irritation	2.6	2.4	3.2
Nausea/vomiting	2.0	4.8	2.6
Asthma symptoms	2.9	7.2	3.3
Cough	2.8	3.6	3.8

Other adverse events that occurred in ≤3% but ≥1% of patients and that were more common with fluticasone propionate with uncertain relationship to treatment included: blood in nasal mucus, runny nose, abdominal pain, diarrhea, fever, flu-like symptoms, aches and pains, dizziness, bronchitis.

Observed During Clinical Practice: In addition to adverse events reported from clinical trials, the following events have been identified during postapproval use of fluticasone propionate in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, causal connection to fluticasone propionate, occurrence during clinical trials, or a combination of these factors.

General: Hypersensitivity reactions, including angioedema, skin rash, edema of the face and tongue, pruritus, urticaria, bronchospasm, wheezing, dyspnea, and anaphylaxis/anaphylactoid reactions, which in rare instances were severe.

Ear, Nose, and Throat: Alteration or loss of sense of taste and/or smell and, rarely, nasal septal perforation, nasal ulcer, sore throat, throat irritation and dryness, cough, hoarseness, and voice changes.

Eye: Dryness and irritation, conjunctivitis, blurred vision, glaucoma, increased intraocular pressure, and cataracts.

OVERDOSAGE: Chronic overdosage with FLONASE Nasal Spray may result in signs/symptoms of hypercorticism (see PRECAUTIONS). Intranasal administration of 2 mg (10 times the recommended dose) of fluticasone propionate twice daily for 7 days to healthy human volunteers was well tolerated. Single oral doses up to 16 mg have been studied in human volunteers with no acute toxic effects reported. Repeat oral doses up to 80 mg daily for 10 days in volunteers and repeat oral doses up to 10 mg daily for 14 days in patients were well tolerated. Adverse reactions were of mild or moderate severity, and incidences were similar in active and placebo treatment groups. Acute overdosage with this dosage form is unlikely since one bottle of FLONASE Nasal Spray contains approximately 8 mg of fluticasone propionate.

The oral and subcutaneous median lethal doses in mice and rats were >1000 mcg/kg (>20000 and >1000 times, respectively, the maximum recommended daily intranasal dose in adults and >10000 and >20000 times, respectively, the maximum recommended daily intranasal dose in children on a mcg/m² basis).

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silver, and gold at the 1997 and '99 world championships—has made her a celebrity, especially among Aborigines, who haven't claimed a high-profile champion since '70s tennis star Evonne Goolagong. NBC first contacted Freeman in 1994, when she and researcher Joe Gesue met in New York. "Many interviews we do are 10 to 15 minutes," says Gesue, now the research team head. "Hers was about an hour and 15 minutes. It was fascinating listening to her story."

He pitched it to Lax, who featured Freeman in Atlanta and followed with an *Olympic Show* piece in 1998. She's a natural for a Sydney update: Australians eagerly await the 400 final, and some Aboriginal groups have threatened to protest at the Games. For this assignment, Lax sought a more personal angle. "I wanted to get to the core of who she is," Lax says. "Her Aboriginality, where she came from and her national heroism."

Lax interviewed Australian sources but couldn't connect with Freeman until the star made a surprise training trip to Los Angeles. Then, Lax says, "she was more candid than ever."

By July, she and editor Meredith Paige had amassed tape covering several years. Shots were digitized and sorted into subject categories, and then Lax spent several long days combining the elements and writing the script. More than five years in the making, the three-minute, 45-second story will air around the time of the Sept. 25 women's 400 final. "Besides being about a great athlete," Lax says, "this piece has texture, history and depth. It's a really rich story." —B.W.