FLONASE is indicated for management of seasonal and perennial allergic rhinitis in patients 12 years and older. It is not indicated for nonallergic rhinitis.

*Claritin® (loratadine) is a registered trademark of Schering Corp.
by a clear nose...

More nasal symptom-free days than Claritin®
In seasonal allergic rhinitis (SAR)...

<table>
<thead>
<tr>
<th>Patient-Rated Nasal Symptom-Free Days</th>
<th>Over 4 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>10%</td>
</tr>
<tr>
<td>20%</td>
<td>30%</td>
</tr>
<tr>
<td>4% Claritin</td>
<td>21% FLONASE</td>
</tr>
</tbody>
</table>

Mean Percentage

Patients evaluated the following symptoms daily: daytime obstruction, rhinorrhea, sneezing, and itching.
† A multicenter, randomized, double-blind, double-dummy, parallel-group, 4-week study in 102 patients with SAR comparing FLONASE 200 µg QD and loratadine 10 mg QD.
‡ In a second multicenter, randomized, double-blind, double-dummy, parallel-group, 4-week study in 240 adolescent patients with SAR comparing FLONASE 200 µg QD and loratadine 10 mg QD. FLONASE demonstrated a significantly higher percentage of symptom-free days (20.5%) than loratadine (8.9%). P<0.001.

At a cost per day 30% less than Claritin®

<table>
<thead>
<tr>
<th></th>
<th>Adult Daily Dosage</th>
<th>AWP$</th>
<th>Cost Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claritin tablets</td>
<td>1 tablet QD</td>
<td>$193.54</td>
<td>1.94</td>
</tr>
<tr>
<td>FLONASE 120 actuations</td>
<td>one to two sprays/nostril QD</td>
<td>$40.63</td>
<td>.68</td>
</tr>
</tbody>
</table>

$ Average wholesale price (AWP) based on Redbook® November 1995. Prices presented may not necessarily reflect the actual prices paid by health care facilities or consumers.

Claritin Tablets exhibit an antihistaminic effect beginning within 1.3 hours, reaching its maximum at 8-12 hours.

A decrease in nasal symptoms has been noted in some patients 12 hours after initial treatment with FLONASE Nasal Spray. Maximum benefit may not be reached for several days. Effectiveness depends on regular use.

Side effects occurring at >1% (causal relationship possible) included epistaxis and nasal burning (3% to 6%) and nasal irritation, headache, and pharyngitis (1% to 3%).

Focused Relief Once a Day...

FLONASE®
(fluticasone propionate) QD AQ

NASAL SPRAY, 0.05%

ANTI-RHINITIC™ Benefits by Molecular Design

Please consult Brief Summary of Prescribing Information for FLONASE on adjacent page.
Flonase®
(fluticasone propionate)
Nasal Spray, 0.05% w/w

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 glucocorticoid with a topical glucocorticoid can be accompanied by signs of adrenal insufficiency, and in addition some patients may experience symptoms of adrenal insufficiency, e.g., joint or muscular pain, lassitude, and depression. Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical glucocorticoids should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical conditions requiring long-term systemic glucocorticoid treatment, too rapid a decrease in systemic glucocorticoid dosage may cause exacerbated asthma or other adverse effects.

The use of Flonase® Nasal Spray with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (HPA) suppression compared with a therapeutic dose of either one alone. Therefore, Flonase Nasal Spray should be used with caution in patients already receiving alternate-day prednisone treatment for any disease. In addition, the concomitant use of Flonase Nasal Spray with other inhaled glucocorticoids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis.

Patients who are on immunosuppressant drugs are more susceptible to infections than healthy individuals. Changes in measures, e.g., can have a more serious or even fatal course in patients on immunosuppressant doses of corticosteroids, in such patients who do not have other 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 prophylactic administration of immune globulin (IG) may be indicated. (See the respective package insert 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 intranasal administration of Flonase® Nasal Spray. Rare instances of wheezing, nasal septum perforation, or epistaxis, glaucoma, and increased intracranial pressure have been reported following the intranasal application of glucocorticoids.

Use of excessive doses of glucocorticoids may lead to signs or symptoms of hypercorticism, suppression of HPA function, and/or suppression of growth in children or teenagers. Overdosage studies in asthmatic children who were normally dosed with glucocorticoids showed depressive effects on short-term growth rate. The relationship between short-term changes in lower leg growth and long-term effects on growth is unclear at this time. Physicians should closely follow the growth of adolescents taking glucocorticoids, by any route, and weigh the benefits of glucocorticoid therapy against the possibility of growth suppression if an adolescent's growth pattern is abnormal.

Although systemic effects have been minimal with recommended doses of Flonase® Nasal Spray, potential risks do exist with larger doses. Therefore, larger than recommended doses of Flonase Nasal Spray should be avoided.

When used at larger doses, systemic glucocorticoid 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 glucocorticoid therapy.

In clinical studies with fluticasone propionate administered intranasally, the development of localized infections of the nose and pharynx with Candida albicans has occurred 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 who have not been using the product for over one month 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 who have active or quiescent tuberculous infections; untreated fungal, bacterial, or systemic viral infections; or ocular herpes simplex.

Because of the intranasal effect of glucocorticoids on wound healing, patients who have experienced recent nasal septal ulcers, nasal surgery, or nasal trauma should not use a nasocutaneous compound until healing has occurred.

Information for Patients: Patients being treated with Flonase Nasal Spray should receive the following information before and during therapy:

1. The effects of the medication are intended to be local, in the safe and effective use of this medication. This is not a disclosure of all possible adverse or intended effects.

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

3. 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.

4. For the proper use of the nasal spray to attain maximum improvement, the patient should read and follow carefully the patient's instructions accompanying the product.

5. Congenital Factors, Mutagenesis, Impairment of Fertility: Fluticasone propionate demonstrated no tumorigenic potential in studies of oral doses up to 1 mg/kg (3 mg/m²) as calculated on a surface area basis) for 78 weeks in the mouse or inhalation of up to 57 mg/kg (336 mg/m²) for 104 weeks in the rat. 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 vitro or in the mouse micronucleus test when administered at high doses by the oral or subcutaneous routes. Furthermore, the compound did not delay erythroblast division in bone marrow.

6. No evidence of impairment of fertility was observed in reproductive studies conducted in rats dosed subacutely with doses up to 50 mg/kg (306 mg/m²) in males and females. However, gestation weight was significantly reduced in rats.

7. Pregnancy: Teratogenic Effects: Pregnancy Category C: Subcutaneous studies in the mouse and rat at 45 and 60 mg/kg (155 and 590 mg/m², respectively, as calculated on a surface area basis) revealed fetal teratogenic characteristic of potent glucocorticoid compounds, including embryonic growth retardation, resorption, cleft palate, and retarded cranial ossification. In the rabbit, fetal weight reduction and cleft palate were observed following subcutaneous doses of 4 mg/kg (6 mg/m²).

However, oral administration of up to 300 mg/kg (510 mg/m²) of fluticasone propionate to the rabbit, there were no maternal effects or increased incidence of external, visceral, or skeletal fetal defects. No fluticasone propionate was detected in the plasma in this study, consistent with the established low bioavailability following oral administration of Flonase® (FLONASE®) (see section of the full prescribing information).

Less than 0.005% of the dose crosses the placenta following oral administration to rats (100 mg/kg, 590 mg/m²) or rabbits (300 mg/kg, 510 mg/m²).

Reference:
1. Data on file, Glaxo Wellcome, Inc.

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Action: Yohimbine blocks presynaptic alpha 2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of shorter duration. Yohimbine's peripheral noradrenergic neuron system effects is to increase para sympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to parasympathetic activity and to alpha 2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow and both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormones.

Dose and Administration: Yohimbine is indicated as a sympatholytic and mydriatic. It may have activity as an aphrodisiac.

Contraindications: Renal disease, and patients sensitive to the drug. To view the full label, Yohimbine is metabolized in the liver, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric, or cardiac patients with other congenital heart disease. No should be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Advise Reactions: Yohimbine rapidly penetrates the CNS and produces a complex pattern of responses to lower doses than required to produce peripheral alpha-adrenergic blockade. These include anti-diuretic, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Swallowing, nausea and vomiting are common after parenteral administration of the drug. Also diziness, headache, skin flushing reported when used orally. Yohimbine is indicated as a sympatholytic and mydriatic. It may have activity as an aphrodisiac.

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Dosing and Administration: Experimental dosage reported in treatment of erectile impotence: 1 tablet (1.5 mg) 3 times daily, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1 tablet 3 times a day, followed by gradual increase to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.

How Supplied: Oral tablets of YOHCON 1/8 112 mg or 5.4 mg in bottles of 100's NDC 35159-001-01, 1000's NDC 35159-001-10 and blister packs of 30's NDC 35159-001-30

References:
1. A. Morales et al., New England Journal of Medicine, 1211, November 12, 1981.

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