Flonase (fluticasone propionate) - Drug Summary

GlaxoSmithKline LLC

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Flonase (fluticasone propionate)

THERAPEUTIC CLASS

Corticosteroid

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Perennial Nonallergic Rhinitis

Initial: 2 sprays/nostril qd or 1 spray/nostril bid
Maint: 1 spray/nostril qd
Max: 2 sprays/nostril qd (200mcg/day)

PEDIATRIC DOSAGE & INDICATIONS

Perennial Nonallergic Rhinitis

≥4 Years:
Initial: 1 spray/nostril qd
Titrate: May increase to 2 sprays/nostril qd if response is inadequate, then return to 1 spray/nostril qd once adequate control is achieved
Max: 2 sprays/nostril qd (200mcg/day)

DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

ADMINISTRATION

Intranasal route

Shake gently before each use

Priming
Prime before using for the 1st time or after a period of non-use (≥1 week) by shaking the contents well and releasing 6 sprays into the air, away from the face

HOW SUPPLIED

Spray: 50mcg/spray [120 sprays]

CONTRAINDICATIONS

Hypersensitivity to any of its ingredients.

WARNINGS/PRECAUTIONS

May cause local nasal effects (eg, epistaxis, nasal ulceration, *Candida* infections, nasal septum perforation, impaired wound healing). When localized infections of the nose and pharynx with *Candida albicans* develop, may need to treat and d/c therapy. Avoid with recent nasal ulcers, nasal surgery, or nasal trauma until healing has occurred. Glaucoma and/or cataracts may develop; closely monitor patients with a change in vision or with a history of increased IOP, glaucoma, and/or cataracts. Hypersensitivity reactions reported; d/c if such reactions occur. May increase susceptibility to infections, caution with active or quiescent TB, systemic fungal, bacterial,

viral or parasitic infections; or ocular herpes simplex. Avoid exposure to chickenpox and measles. D/C slowly if hypercorticism and adrenal suppression occur. Risk of adrenal insufficiency and withdrawal symptoms when replacing systemic corticosteroids with topical corticosteroids. May reduce growth velocity in pediatric patients. Caution with hepatic disease.

ADVERSE REACTIONS

Headache, pharyngitis, epistaxis, nasal burning/irritation, N/V, asthma symptoms, cough.

DRUG INTERACTIONS

Not recommended with strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, ketoconazole); increased systemic corticosteroid adverse effects may occur.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Corticosteroid; not established. Shown to have a wide range of effects on multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (eg, histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation.

PHARMACOKINETICS

Absorption: Absolute bioavailability (<2%). **Distribution:** (IV) V_d=4.2L/kg; plasma protein binding (99%). **Metabolism:** Liver via CYP3A4. **Elimination:** (Oral) Urine (<5% metabolites), feces (unchanged and metabolites); (IV) $T_{1/2}$=7.8 hrs.

ASSESSMENT

Assess for drug hypersensitivity, active or quiescent TB, systemic fungal/bacterial/viral/parasitic infections, ocular herpes simplex, recent nasal ulcers/surgery/trauma, history of increased IOP, glaucoma, or cataracts, hepatic disease, pregnancy/nursing status, and possible drug interactions. Assess if patients have not been immunized or exposed to infections, such as measles or chickenpox.

MONITORING

Monitor for epistaxis, nasal ulceration, nasal septal perforation, impaired wound healing, changes in vision, glaucoma, cataracts, hypersensitivity reactions, infections (eg, chickenpox, measles), hypercorticism, adrenal suppression, hypoadrenalism (in infants born of mothers receiving corticosteroids during pregnancy), and other adverse reactions. Examine periodically for evidence of nasal *Candida* infections. Routinely monitor growth of pediatric patients. Monitor for adrenal insufficiency and withdrawal symptoms when replacing systemic corticosteroid with topical corticosteroid.

PATIENT COUNSELING

Inform of possible local nasal effects, glaucoma, cataracts, hypersensitivity reactions, immunosuppression, and reduced growth velocity (in pediatric patients). Advise patients who have experienced recent nasal ulcers, surgery, or trauma to not use therapy until healing has occurred. Instruct to notify physician if a change in vision develops, and to d/c therapy if hypersensitivity reactions occur. Instruct to avoid exposure to chickenpox or measles; if exposed, advise to consult physician without delay. Instruct to use spray on a regular basis, and not to increase prescribed dosage; advise to contact physician if symptoms do not improve or if condition worsens. Instruct to avoid spraying in eyes and mouth. Advise women to contact physician if they become pregnant.

STORAGE

4-30°C (39-86°F).

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