Advair Diskus (fluticasone propionate/salmeterol) - Drug Summary

GlaxoSmithKline LLC

Related Drug Information

Advair Diskus (fluticasone propionate/salmeterol)

BOXED WARNING

Long-acting β_2-adrenergic agonists (LABAs), such as salmeterol, increase the risk of asthma-related death. LABAs may increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Use only for patients not adequately controlled on a long-term asthma control medication (eg, inhaled corticosteroid) or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Do not use if asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

View FDA-Approved Full Prescribing Information for Advair Diskus

THERAPEUTIC CLASS

Beta$_2$ agonist/corticosteroid

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Asthma

1 inh bid, approx 12 hrs apart
Titrate: May replace current strength with a higher strength if response to initial dose after 2 weeks is inadequate
Max: 500/50 bid

Chronic Obstructive Pulmonary Disease

Maint Treatment of Airflow Obstruction:
1 inh of 250/50 bid, approx 12 hrs apart

PEDIATRIC DOSAGE & INDICATIONS

Asthma

4-11 Years:
1 inh of 100/50 bid, approx 12 hrs apart

≥12 Years:
1 inh bid, approx 12 hrs apart
Titrate: May replace current strength with a higher strength if response to initial dose after 2 weeks is inadequate
Max: 500/50 bid

ADMINISTRATION

Oral inh route

After inhalation, rinse mouth with water without swallowing

HOW SUPPLIED

Disk: (Fluticasone-Salmeterol) (100/50) 100mcg-50mcg/inh, (250/50) 250mcg-50mcg/inh, (500/50) 500mcg-50mcg/inh [14, 60 blisters]

CONTRAINDICATIONS

Primary treatment of status asthmaticus or other acute episodes of asthma or COPD where intensive measures are required. Milk protein hypersensitivity.

WARNINGS/PRECAUTIONS

Not indicated for acute bronchospasm relief. Do not initiate during rapidly deteriorating or potentially life-threatening episodes of asthma or COPD; serious acute respiratory events reported. D/C regular use of oral/inhaled short-acting β_2-agonists (SABAs) when beginning treatment. Do not use more often or at higher doses than recommended; clinically significant cardiovascular (CV) effects and fatalities reported with excessive use. *Candida albicans* infections of mouth and pharynx reported; treat and if needed, interrupt therapy. Lower respiratory tract infections (eg, pneumonia) reported in patients with COPD. Increased susceptibility to infections. May lead to serious/fatal course of chickenpox or measles; avoid exposure and, if exposed, consider prophylaxis/treatment. Caution with active/quiescent tuberculosis (TB), systemic fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex. Deaths due to adrenal insufficiency reported during and after transfer from systemic to inhaled corticosteroids; wean slowly from systemic corticosteroid use after transferring to therapy. Resume oral corticosteroids during periods of stress or a severe asthma attack in patients previously withdrawn from systemic corticosteroids. Transfer from systemic to inhaled corticosteroids may unmask allergic conditions previously suppressed by systemic therapy (eg, rhinitis, conjunctivitis, eczema). Monitor for systemic corticosteroid effects. Reduce dose slowly and consider other treatments if hypercorticism and adrenal suppression occur. May produce paradoxical bronchospasm; treat immediately with an inhaled, short acting bronchodilator; d/c and institute alternative therapy. Upper airway symptoms reported. Immediate hypersensitivity reactions, and CV and CNS effects may occur. Decreases in bone mineral density (BMD) reported with long-term use; caution with major risk factors for decreased bone mineral content, including chronic use of drugs that can reduce bone mass (eg, anticonvulsants, oral corticosteroids). Assess BMD prior to initiating therapy and periodically thereafter in patients with COPD; if significant reductions in BMD are seen and therapy is still considered medically important, use medicine to treat or prevent osteoporosis. May reduce growth velocity in pediatric patients; routinely monitor growth. Glaucoma, increased intraocular pressure (IOP), and cataracts reported with long-term use. Systemic eosinophilic conditions, and vasculitis consistent with Churg-Strauss syndrome may occur. Caution with CV disorders, convulsive disorders, thyrotoxicosis, diabetes mellitus (DM), ketoacidosis, hepatic disease, and in patients unusually responsive to sympathomimetic amines. Clinically significant changes in blood glucose and/or serum K^+ reported.

ADVERSE REACTIONS

Upper respiratory tract infection/inflammation, pharyngitis, hoarseness/dysphonia, bronchitis, cough, headache, N/V, sinusitis, throat irritation, viral respiratory infection, musculoskeletal pain, fever, dizziness.

DRUG INTERACTIONS

Do not use with other medicines containing LABA. Not recommended with strong CYP3A4 inhibitors (eg, ritonavir, clarithromycin, itraconazole); increased systemic corticosteroid and increased CV adverse effects may occur. Extreme caution with TCAs or MAOIs, or within 2 weeks of discontinuation of such agents; action on the vascular system may be potentiated. β-blockers may block pulmonary effects and produce severe bronchospasm; if such therapy is needed, consider cardioselective β-blockers and use with caution. Caution is advised when coadministered with non-K^+-sparing diuretics (eg, loop, thiazide).

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Fluticasone: Corticosteroid; effects in COPD treatment not established. Shown to have a wide range of actions on multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (eg, histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. Salmeterol: Selective LABA; attributable to stimulation of intracellular adenyl cyclase, the enzyme that catalyzes the conversion of ATP to cAMP. Increased cAMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

PHARMACOKINETICS

Absorption: Administration of multiple doses in healthy, asthmatic, and COPD patients resulted in different pharmacokinetic parameters. **Distribution:** Fluticasone: V_d=4.2L/kg (IV); plasma protein binding (99%). Salmeterol: Plasma protein binding (96%). **Metabolism:** Fluticasone: Liver via CYP3A4; 17β-carboxylic acid derivative (metabolite). Salmeterol: Liver (extensive) by hydroxylation; α-hydroxysalmeterol (aliphatic oxidation) via CYP3A4. **Elimination:** Fluticasone: Urine (<5%, metabolites), feces (unchanged and metabolites); $T_{1/2}$=5.6 hrs. Salmeterol: Urine (25%), feces (60%); $T_{1/2}$=5.5 hrs.

ASSESSMENT

Assess for hypersensitivity to milk proteins, status asthmaticus, acute asthma/COPD episodes, rapidly deteriorating asthma/COPD, active/quiescent TB, systemic infections, ocular herpes simplex, risk factors for decreased bone mineral content, CV disorders, convulsive disorders, thyrotoxicosis, DM, ketoacidosis, history of increased IOP, glaucoma, and/or cataracts, hepatic disease, pregnancy/nursing status, and possible drug interactions. Assess BMD in patients with COPD.

MONITORING

Monitor for deteriorating disease, localized oropharyngeal *C. albicans* infections, pneumonia, infections, systemic corticosteroid effects (eg, hypercorticism, adrenal suppression), paradoxical bronchospasm, upper airway symptoms, immediate hypersensitivity reactions, CV and CNS effects, glaucoma, cataracts, increased IOP, eosinophilic conditions, changes in blood glucose and/or serum K^+, and other adverse reactions. Periodically monitor BMD in patients with COPD. Monitor growth of pediatric patients routinely. Closely monitor patients with hepatic disease.

PATIENT COUNSELING

Counsel about the risks and benefits of therapy. Inform that drug is not meant to relieve acute asthma symptoms or exacerbations of COPD; advise to treat acute symptoms with an inhaled SABA (eg, albuterol). Instruct to seek medical attention immediately if experiencing a decrease in effectiveness of inhaled SABAs, a need for more inhalations than usual of inhaled SABAs, or a significant decrease in lung function. Advise not to d/c therapy without physician guidance and not to use other LABA. Instruct to contact physician if oropharyngeal candidiasis or symptoms of pneumonia develop. Advise to avoid exposure to chickenpox or measles, and, if exposed, to consult physician without delay. Inform about risk of immunosuppression, hypercorticism, adrenal suppression, reduction in BMD, reduced growth velocity in pediatric patients, ocular effects, and of adverse effects (eg, palpitations, chest pain, rapid HR, tremor, nervousness). Instruct to d/c therapy if immediate hypersensitivity reactions occur. Inform that the inhaler is not reusable and advise not to take the inhaler apart.

STORAGE

20-25°C (68-77°F); excursions permitted from 15-30°C (59-86°F). Store in a dry place away from direct heat or sunlight. Store inside the unopened moisture-protective foil pouch and only remove from the pouch immediately before initial use. Discard 1 month after opening the foil pouch or when the counter reads "0," whichever comes 1st.

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