Symbicort (budesonide/formoterol fumarate dihydrate) - Drug Summary

AstraZeneca LP

Related Drug Information ▼

Symbicort
(budesonide/formoterol fumarate dihydrate)

BOXED WARNING

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

THERAPEUTIC CLASS

$Beta_2$ agonist/corticosteroid

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Asthma

2 inh bid (am and pm, approx q12h)
Initial: Based on severity
Max: 160mcg/4.5mcg/inh bid

Not Responding After 1-2 Weeks of Therapy w/ 80mcg/4.5mcg/inh:
Replace w/ 160mcg/4.5mcg/inh for better asthma control

Chronic Obstructive Pulmonary Disease

Maint Treatment of Airflow Obstruction:
2 inh (160mcg/4.5mcg/inh) bid

PEDIATRIC DOSAGE & INDICATIONS

Asthma

≥12 Years:
2 inh bid (am and pm, approx q12h)
Initial: Based on severity
Max: 160mcg/4.5mcg/inh bid

Not Responding After 1-2 Weeks of Therapy w/ 80mcg/4.5mcg/inh:
Replace w/ 160mcg/4.5mcg/inh for better asthma control

ADMINISTRATION

Oral inh route

After inh, rinse mouth w/ water w/o swallowing
Shake well for 5 sec before use

Priming
1. Shake the inhaler well for 5 sec
2. Hold the inhaler pointing away from the face and then release a test spray
3. Shake it again for 5 sec and release a 2nd test spray
4. Depending on which size was provided, the counter will read either 120 or 60 after it has been primed

If inhaler is not used for more than 7 days or if it is dropped, prime again

HOW SUPPLIED

MDI: (Budesonide/Formoterol) 80mcg/4.5mcg/inh, 160mcg/4.5mcg/inh [60 inhalations, 120 inhalations]

CONTRAINDICATIONS

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

WARNINGS/PRECAUTIONS

Not indicated for the relief of acute bronchospasm; take inhaled short-acting β_2-agonists (SABAs) for immediate relief. Do not initiate during rapidly deteriorating/potentially life-threatening asthma or COPD. D/C regular use of oral/inhaled SABAs when beginning treatment. Cardiovascular (CV) effects and fatalities reported with excessive use; do not use more often or at higher doses than recommended. *Candida albicans* infections of the mouth and pharynx reported; treat with appropriate local or systemic (eg, antifungal) therapy or, interrupt therapy if needed. 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); untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. Deaths due to adrenal insufficiency reported with transfer from systemic to inhaled corticosteroids; if systemic corticosteroids are required, wean slowly from systemic steroid after transferring to therapy. Resume oral corticosteroids during periods of stress or a severe asthma attack if patient was previously withdrawn from systemic corticosteroid. Carefully monitor during withdrawal of oral corticosteroid. Transferring from systemic to inhalation therapy may unmask previously suppressed allergic conditions (eg, rhinitis, conjunctivitis, eczema, arthritis, eosinophilic conditions); monitor for systemic corticosteroid withdrawal effects. Observe carefully for any evidence of systemic corticosteroid effects; caution should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response. Reduce dose slowly if hypercorticism or adrenal suppression (including adrenal crisis) appears. May produce paradoxical bronchospasm; d/c immediately and institute alternative therapy. Immediate hypersensitivity reactions (eg, urticaria, angioedema, rash, bronchospasm) may occur. Caution with CV disorders (eg, coronary insufficiency, cardiac arrhythmias, HTN). Decreases in bone mineral density (BMD) reported; caution with major risk factors for decreased bone mineral content (eg, prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, advanced age, poor nutrition). May reduce growth velocity in pediatrics; use lowest effective dose. Glaucoma, increased IOP, cataracts, rare cases of systemic eosinophilic conditions, and vasculitis consistent with Churg-Strauss syndrome reported. Caution with convulsive disorders, thyrotoxicosis, diabetes mellitus (DM), ketoacidosis, hepatic impairment, and in patients unusually responsive to sympathomimetic amines. Clinically significant changes in blood glucose and/or serum K^+ reported. Caution in elderly.

ADVERSE REACTIONS

Nasopharyngitis, headache, URTI, pharyngolaryngeal pain, sinusitis, influenza, back pain, nasal congestion, stomach discomfort, oral candidiasis, bronchitis, vomiting.

DRUG INTERACTIONS

Do not use with other medications containing LABAs (eg, salmeterol, formoterol fumarate, arformoterol tartrate); increased risk of CV effects. Caution with ketoconazole, other known strong CYP3A4 inhibitors (eg, ritonavir, nefazodone, telithromycin, itraconazole), and non-K^+-sparing diuretics (eg, loop, thiazide). Caution with MAOIs or TCAs, or within 2 weeks of discontinuation of such agents. Concomitant use with β-blockers may produce severe bronchospasm in patients with asthma; consider cardioselective β-blockers and administer with caution. Caution with chronic use of drugs that can reduce bone mass (eg, anticonvulsants, oral corticosteroids).

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Budesonide: Corticosteroid; shown to have inhibitory activities on multiple cell types and mediators involved in allergic and nonallergic mediated inflammation. Formoterol: LABA; attributable to stimulation of intracellular adenyl cyclase, 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 mast cells.

PHARMACOKINETICS

Absorption: Rapid. Administration of various doses resulted in different pharmacokinetic parameters. **Distribution:** Budesonide: V_d=3L/kg; plasma protein binding (85-90%). Formoterol: Plasma protein binding (RR enantiomer, 46%), (SS enantiomer, 58%). **Metabolism:** Budesonide: Liver (rapid and extensive) via CYP3A4. Formoterol: Liver (direct glucuronidation and O-demethylation) via CYP2D6, CYP2C. **Elimination:** Budesonide: Urine (60%); feces. $T_{1/2}$=2-3 hrs. Formoterol: (Healthy) Urine (62%); feces (24%).

ASSESSMENT

Assess use of long-term asthma control medication (eg, inhaled corticosteroids), status asthmaticus, acute asthma episodes, rapidly deteriorating asthma, bronchospasm, known hypersensitivity to any component of drug, risk factors for decreased bone mineral content, CV or convulsive disorders, other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions. Assess use in patients unusually responsive to sympathomimetic amines. Obtain baseline BMD, eye exam, and lung function.

MONITORING

Monitor for localized oral *C. albicans* infections, worsening or acutely deteriorating asthma, development of glaucoma, increased IOP, cataracts, CV/CNS effects, inhalation induced paradoxical bronchospasm,

pneumonia, lower respiratory tract in patients with COPD, hypercorticism, adrenal suppression, hypersensitivity reactions, signs of increased drug exposure with hepatic impairment, and other adverse reactions. Monitor lung function, pulse rate, BP, ECG changes, blood glucose, and serum K^+ levels. Monitor BMD periodically. Monitor growth in children.

PATIENT COUNSELING

Inform about increased risk of asthma-related death/hospitalization in pediatrics and adolescents. Instruct not to use to relieve acute asthma symptoms; treat acute symptoms with an inhaled SABA for immediate relief. Instruct to notify physician immediately if experiencing decreased effectiveness of inhaled SABA, need for more inhalations of inhaled SABA than usual, or significant decrease in lung function. Instruct not to d/c without physician's guidance. Instruct not to use with other LABA for asthma and COPD. Advise that localized infections with *C. albicans* may occur in the mouth and pharynx. Instruct to contact physician if symptoms of pneumonia develop. Instruct to avoid exposure to chickenpox or measles and to consult physician without delay, if exposed. Inform of potential worsening of existing TB, fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex. Inform about risks of hypercorticism and adrenal suppression, decreased BMD, cataracts or glaucoma, and reduced growth velocity in pediatric patients. Instruct to taper slowly from systemic corticosteroids if transferring to budesonide-formoterol. Inform of adverse effects associated with β_2-agonists (eg, palpitations, chest pain, rapid HR, tremor, nervousness).

STORAGE

20-25°C (68-77°F). Store with mouthpiece down. Contents under pressure; do not puncture, incinerate, or store near heat or open flame. Discard when labeled number of inhalations have been used or within 3 months after removal from pouch.

Back to top