



Asmanex

(Mometasone Furoate) - Merck

THERAPEUTIC CLASS

Corticosteroid

DEA CLASS

RX

INDICATIONS

Maintenance treatment of asthma as prophylactic therapy in patients ≥ 4 yrs of age.

ADULT DOSAGE

Adults: Previous Therapy with Bronchodilators Alone or Inhaled Corticosteroids: Initial: 220mcg qpm. Max: 440mcg qpm or 220mcg bid. Previous Therapy with Oral Corticosteroids: Initial: 440mcg bid. Max: 880mcg/day. Titrate: May give higher dose if response is inadequate after 2 weeks. Adjust to lowest effective dose once asthma stability is achieved.

PEDIATRIC DOSAGE

Pediatrics: ≥ 12 Yrs: Previous Therapy with Bronchodilators Alone or Inhaled Corticosteroids: Initial: 220mcg qpm. Max: 440mcg qpm or 220mcg bid. Previous Therapy with Oral Corticosteroids: Initial: 440mcg bid. Max: 880mcg/day. Titrate: May give higher dose if response is inadequate after 2 weeks. Adjust to lowest effective dose once asthma stability is achieved. 4-11 Yrs: Initial/Max: 110mcg qpm regardless of prior therapy.

HOW SUPPLIED

Powder, Inhalation: 110mcg/actuation, 220mcg/actuation

CONTRAINDICATIONS

Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. Hypersensitivity to milk proteins.

WARNINGS/PRECAUTIONS

Not for the relief of acute bronchospasm. Localized *Candida albicans* infections of the mouth and pharynx reported; treat accordingly or interrupt therapy if needed. D/C if hypersensitivity reactions occur. Contains small amount of lactose that contains milk proteins; anaphylactic reactions with milk protein allergy reported. May increase susceptibility to infections; caution with active or quiescent tuberculosis (TB) infection, untreated systemic fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex. Avoid exposure to chickenpox and measles. Deaths due to adrenal insufficiency have occurred with transfer from systemic to inhaled corticosteroids; wean slowly from systemic corticosteroid therapy. Resume oral corticosteroids immediately during periods of stress or severe asthma attack. Transferring from systemic corticosteroid may unmask allergic conditions (eg, rhinitis, conjunctivitis, eczema, arthritis, eosinophilic conditions). Monitor for systemic corticosteroid effects, such as hypercorticism and adrenal suppression; reduce dose slowly when the effects occur. Prolonged use may result in decrease of bone mineral density (BMD); caution in patients at risk (eg, prolonged immobilization, family history of osteoporosis, chronic use of drugs that reduce bone mass [eg, anticonvulsants, corticosteroids]). May cause reduction in growth velocity in pediatric patients; monitor growth routinely. Glaucoma, increased intraocular pressure (IOP), and cataracts reported. Bronchospasm may occur with an increase in wheezing after dosing; d/c treatment and institute alternative therapy.

ADVERSE REACTIONS

Headache, allergic rhinitis, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, dysmenorrhea, musculoskeletal pain, back pain, dyspepsia, myalgia, abdominal pain, nausea.

DRUG INTERACTIONS

Ketoconazole may increase plasma levels.

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

Corticosteroid; not established. Shown to have inhibitory effects on multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (eg, histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammatory and asthmatic response.

PHARMACOKINETICS

Absorption: Absolute bioavailability (<1%); C_{max} =94-114pcg/mL; T_{max} =1-2.5 hrs. **Distribution:** (IV) V_d =152L; plasma protein binding (98-99%). **Metabolism:** Liver via CYP3A4. **Elimination:** Feces (74%), urine (8%); (IV) $T_{1/2}$ =5 hrs.

ASSESSMENT

Assess for status asthmaticus, acute asthma episodes, known hypersensitivity to milk proteins or to any drug component, risk factors for decreased BMD, history of increased IOP/glaucoma/ataracts, active or quiescent pulmonary TB, ocular herpes simplex, untreated systemic infections, chickenpox, measles, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for localized infections of mouth and pharynx with *C. albicans*, decreased BMD, asthma instability, growth in pediatrics routinely, development of glaucoma, increased IOP, cataracts, change in vision, hypercorticism, signs and symptoms of adrenal insufficiency, paradoxical bronchospasm, hypersensitivity reactions, and immunosuppression. Monitor for lung function, β -agonist use, and asthma symptoms during withdrawal of oral corticosteroids

PATIENT COUNSELING

Advise that localized infection with *C. albicans* may occur in mouth and pharynx; instruct to rinse mouth after inhalation. Inform that therapy should not be used to treat status asthmaticus or to relieve acute asthma symptoms. Counsel to d/c if hypersensitivity reactions occur. Advise to avoid exposure to chickenpox or measles and to seek medical attention if exposed. Inform of potential worsening of existing TB, other infections, or ocular herpes simplex. Inform that drug may cause systemic corticosteroid effects of hypercorticism and adrenal suppression, may reduce BMD, and may cause reduction in growth rate (pediatrics). Advise to take ud, to use medication at regular intervals, and to contact physician if symptoms do not improve or if condition worsens. Instruct on proper administration procedures and on when to discard inhaler.

ADMINISTRATION/STORAGE

Administration: Oral inhalation. Inhale rapidly and deeply. Rinse mouth after inhalation. Refer to PI for further administration instructions.

Storage: 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Store in dry place. Discard inhaler 45 days after opening foil pouch or when dose counter reads "00," whichever comes 1st.