

BUDESONIDE:

Class: Corticosteroid , inhalant

Indications:

Maintenance and prophylactic treatment of asthma.

Available dosage form in the hospital:

- BUDESONIDE 500MCG SUSP. FOR NEBULIZATION
- BUDESONIDE 100MCG/DOSE N/SPRAY
- BUDESONIDE 200MCG TURBUHALER
- BUDESONIDE 64 MCG/DOSE NASAL SPRAY

Dosage:

-Asthma: Oral Inhalation: Titrate to lowest effective dose once patient is stable.

-*U.S. labeling* : Pulmicort flexhaler®: :Initial :360 mcg twice daily (selected patients may be initiated at 180 mcg daily) ; maximum : 720 mcg twice daily ;**Note** : may increase dose after 1-2 weeks of therapy in patient who are not adequately controlled.

- NIH Asthma Guidelines (NIH, 2007) (administer in divided doses twice daily):

- "Low" dose: 180-600 mcg/day
- "Medium" dose :> 600-1200 mcg/day
- "High" dose : >1200 mcg/day

-Canadian labeling: Pulmicort® Turbuhaler®:

-Initial (or during periods of severe asthma or when switching from oral corticosteroid therapy): 400-2400 mcg daily in 2-4 divided doses

-Maintenance: 200-400 mcg twice daily (higher doses may be needed for some patients). Patients taking 400 mcg/day may take as a single daily dose.

-Conversion from oral systemic corticosteroid to orally inhaled corticosteroid: Initiation of oral inhalation therapy should begin in patients whose asthma is reasonably stabilized on oral corticosteroids (OCS). A gradual dose reduction of OCS should begin ~7-10 days after starting inhaled therapy. U.S. labeling recommends reducing prednisone dose by 2.5 mg/day (or equivalent of other OCS) on a weekly basis (patients using oral inhaler) or by ≤25% every 1-2 weeks (patients using respules). Canadian labeling recommends reducing prednisone dose by 2.5 mg/day (or equivalent of other OCS) every 4 days in closely monitored patients or every 10 days if not closely monitored. If adrenal insufficiency occurs, temporarily increase the OCS dose and follow with a more gradual withdrawal. **Note:** When transitioning from systemic to inhaled corticosteroids, supplemental systemic corticosteroid therapy may be necessary during periods of stress or during severe asthma attacks.

-Nebulization:Pediatric: Pulmicort Respules®: Children 12 months to 8 years: Titrate to lowest effective dose once patient is stable; start at 0.25 mg/day or use as follows:

- Previous therapy of bronchodilators alone: 0.5 mg/day administered as a single dose or divided twice daily (maximum daily dose: 0.5 mg)
- Previous therapy of inhaled corticosteroids: 0.5 mg/day administered as a single dose or divided twice daily (maximum daily dose: 1 mg)
- Previous therapy of oral corticosteroids: 1 mg/day administered as a single dose or divided twice daily (maximum daily dose: 1 mg)

-NIH Asthma Guidelines (NIH, 2007):

-Children 0-4 years:

“Low” dose: 0.25-0.5 mg/day

“Medium” dose: >0.5-1 mg/day

“High” dose: >1 mg/day

-Children 5-11 years:

“Low” dose: 0.5 mg/day

“Medium” dose: 1 mg/day

“High” dose: 2 mg/day

Geriatric

Refer to adult dosing.

Renal Impairment:

Inhalation, Nebulization, Oral: No dosage adjustment provided in manufacturer’s labeling (has not been studied).

Hepatic Impairment:

Inhalation, Nebulization, Oral: No specific dosage adjustment provided in manufacturer’s labeling (has not been studied). Manufacturer labeling for oral budesonide suggests a dosage reduction may be necessary with moderate to severe impairment. Budesonide undergoes hepatic metabolism; bioavailability increased in cirrhosis; monitor closely for signs and symptoms of hypercorticism.

Common side effect:

-Oral inhaler (Pulmicort Flexhaler®):

Cardiovascular: Syncope (1% to 3%)

Central nervous system: Fever ($\geq 3\%$), headache ($\geq 3\%$), pain ($\geq 3\%$), insomnia (1% to 3%)

Dermatologic: Bruising (1% to 3%)

Gastrointestinal: Dyspepsia ($\geq 5\%$), nausea (2% to $\geq 5\%$), abdominal pain (1% to 3%), taste perversion (1% to 3%), vomiting (1% to 3%), weight gain (1% to 3%), xerostomia (1% to 3%), gastroenteritis (viral; 2%), oral candidiasis (1%)

Neuromuscular & skeletal: Arthralgia ($\geq 5\%$), weakness ($\geq 5\%$), back pain ($\geq 3\%$), fracture (1% to 3%), hypertonia (1% to 3%), myalgia (1% to 3%), neck pain (1% to 3%)

Otic: Otitis media (1%)

Respiratory: Nasopharyngitis (9%), cough ($\geq 5\%$), rhinitis ($\geq 5\%$), respiratory infection ($\geq 3\%$), sinusitis ($\geq 3\%$), nasal congestion (3%), pharyngitis (3%), allergic rhinitis (2%), upper respiratory tract infection (viral; 2%)

Miscellaneous: Infection (1% to 3%), voice alteration (1% to 3%)

-Suspension for nebulization:

Otic : otitis media

Respiratory : Respiratory infection , rhinitis

Pregnancy Risk Factor: C (capsule, tablet)/B (inhalation)