# Summary of NAEPP's EPR-3: Recommended Medications for Asthma*

| *Long-Term Control Medications for Children Ages 5-11 Years* | | | |
|---|---|---|---|
| **Medication** | **Estimated Daily Dose** | | |
| **Inhaled Corticosteroid (ICS)** | **Low** | **Medium** | **High** |
| **Beclomethasone HFA** 40 or 80 mcg/puff | 80-160 mcg | >160-320 mcg | >320 mcg |
| **Budesonide DPI** 90, 180, or 200 mcg/inhalation | 180-400 mcg | >400-800 mcg | >800 mcg |
| **Budesonide Inhaled Suspension** *for nebulizer* | 0.5 mg | 1.0 mg | 2.0 mg |
| **Flunisolide** 250 mcg/puff | 500-750 mcg | 1000-1250 mcg | >1250 mcg |
| **Flunisolide HFA** 80 mcg/puff | 160 mcg | 320 mcg | ≥640 mcg |
| **Fluticasone HFA/MDI** 44, 110, or 220 mcg/puff | 88-176 mcg | >176-352 mcg | >352 mcg |
| **Fluticasone DPI** 50, 100, or 250 mcg/inhalation | 100-200 mcg | >200-400 mcg | >400 mcg |
| **Mometasone** 200 mcg/inhalation | NA | | |
| **Triamcinolone Acetonide** 75 mcg/puff | NA | | |
| **Medication** | **Usual Doses** | | |
| **Long-Acting Beta$_2$ Agonist (LABA) **** | | | |
| **Salmeterol DPI** 50 mcg/blister | 50 mcg Q 12 hours | | |
| **Formoterol DPI** 12 mcg/single-use capsule | 12 mcg Q 12 hours | | |
| **Combined Medications** | | | |
| **Fluticasone/Salmeterol DPI** 100 mcg/50 mcg | 1 inhalation BID | | |
| **Budesonide/Formoterol HFA MDI** 80 mcg/4.5 mcg | 2 puffs BID | | |
| **Cromolyn/Nedrocromil** | | | |
| **Cromolyn MDI** 0.8mg/puff | 2 puffs BID | | |
| **Cromolyn** *Nebulizer* 20 mg/ampule | 1 ampule QID | | |
| **Nedrocromil MDI** 1.75 mg/puff | 2 puffs QID (NA for < 6 years) | | |
| **Leukotriene Receptor Antagonists (LTRAs)** | | | |
| **Montelukast** 4 or 5 mg chewable tablets; 4 mg granule packets | 5 mg QHS (**6-14 years**) | | |
| **Zafirlukast** 10 mg tablet | NA (**5-6 years**) 10 mg BID (**7-11 years**) | | |
| **Methylxanthines** | | | |
| **Theophylline** liquids, sustained release tablets, and capsules | Starting dose 10mg/kg/day; Usual maximum 16 mg/kg/day | | |
| **Oral Systemic Corticosteroids (OSC)** | | | |
| **Methylprednisolone** 2, 4, 8, 16, 32 mg tablets | 0.25-2.0 mg/kg daily in single dose in a.m. or QOD as needed for control | | |
| **Prednisolone** 5 mg tablets, 5 mg/5 cc, 15 mg/5 cc | | | |
| **Prednisone** 1, 2.5, 5, 10, 20, 50 mg tablets; 5 mg/cc, 5 mg/5 cc | | | |

KEY: CFC-chloroflurocarbon, DPI-dry-powdered inhaler; HFA-hydrofluroalkane; MDI-metered-dose inhaler; NA-not available (safety & efficacy not established for this age group, not approved, or no data available)

NOTE: Dosages are provided for those products that have been approved by the U.S. Food and Drug Administration or have sufficient clinical trial safety and efficacy data in the appropriate age ranges to support their use.

The above list is not all inclusive. Check availability and health plan formulary when applicable.

*** See EPR-3 Full Report for full discussion. See reverse side for additional therapeutic issues.**

****LABA's:** In February 2010 the FDA issued a safety announcement on the use of LABA's. The FDA has concluded that there is an **increased risk for severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients** using LABA's for the treatment of asthma. It is recommended that LABA's only be used in patients whose asthma cannot be adequately controlled on asthma controller medications and should only be used in conjunction with an inhaled corticosteroid. Additional LABA information on reverse side.

Produced by the California Asthma Public Health Initiative (CAPHI). Summarized from the NAEPP EPR-3: www.nhlbi.nih.gov/guidelines/asthma. This summary of NAEPP's recommended stepwise medications for asthma is designed to assist the clinician in the diagnosis and management of asthma and is not intended to replace the clinician's judgment or establish a protocol for all patients with a particular condition. Additional copies of this summary and other asthma resources available at www.betterasthmacare.org. Permission to reprint granted if unaltered. **April 2010**

# Summary of NAEPP's EPR-3: Recommended Medications for Asthma*

## *Long-Term Control Medications for Children Ages 5-11 Years*

**General Therapeutic Issues:**

- The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy. The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.
- For fluticasone HFA, the dose should be divided 2 times daily; the low dose for children <4 years is higher than for children 5–11 years of age due to lower dose delivered with face mask and data on efficacy in young children.
- Preparations are not interchangeable on a mcg or a per puff basis. These figures represent estimated daily doses.
- Some doses may be outside package labeling, especially in the high-dose range.
- Metered-dose inhaler (MDI) dosages are expressed as the actuator dose (the amount of the drug leaving the actuator and delivered to the patient), which is the labeling required in the United States. This is different from the dosage expressed as the valve dose (the amount of drug leaving the valve, not all of which is available to the patient), which is used in many European countries and in some scientific literature. Dry powder inhaler (DPI) doses are expressed as the amount of drug in the inhaler following activation.
- Use of a spacer/holding chamber is recommended with the use of an MDI.
- A number of the ICS's, including fluticasone, budesonide, and mometasone, are metabolized in the gastrointestinal tract and liver by CYP 3A4 isoenzymes. Potent inhibitors of CYP 3A4, such as ritonavir and ketoconazole, have the potential for increasing systemic concentrations of these ICS's by increasing oral availability and decreasing systemic clearance. Some cases of clinically significant Cushing syndrome and secondary adrenal insufficiency have been reported (Johnson et al. 2006; Samaras et al. 2005)
- Salmeterol: Decreased duration of protection against EIB may occur with regular use.
- Formoterol: Each capsule is for single use only; additional doses should not be administered for at least 12 hours. Capsules should be used only with the AerolizorTM inhaler and should not be taken orally.
- Cromolyn & Nedrocromil: 4-6 week trial may be needed to determine maximum benefit. Dose by MDI may be inadequate to affect hyperresponsiveness. One dose before exercise or allergen exposure provides effective prophylaxis for 1-2 hours. Not as effective for EIB as SABA. Once control is achieved, the frequency of dosing may be reduced.
- Montelukast: Exhibits a flat dose-response curve.
- Zafirlukast: Administration with meals decreases bioavailability; take at least 1 hour before or 2 hours after meals. Monitor for signs of hepatic dysfunction.
- Theophylline: Adjust dosage to achieve serum concentration of 5-15 mcg/mL at steady-state (at least 48 hours on the same dosage). Due to wide interpatient variability in theophylline metabolic clearance, routine serum theophylline level monitoring is important. See full EPR-3 guidelines for factors that affect theophylline levels.
- All Three Systemic Corticosteroids: For long-term treatment of severe persistent asthma, administer single dose in a.m. either daily or on alternate days (alternate-day therapy may produce less adrenal suppression). Short courses or "bursts" are effective for establishing control when initiating therapy or during a period of gradual deterioration. There is no evidence that tapering following improvement prevents relapse. Patients receiving the lower dose (1mg/kg/day) experience fewer behavioral side effects (Kayani and Shannon 2002), and it appears to be equally efficacious (Rachelefsky 2003). For patients unable to tolerate the liquid preparations, dexamethasone syrup at 0.4 mg/kg/day may be an alternative. Studies are limited, however, and the longer duration of activity increases the risk of adrenal suppression (Hendeles 2003).
- Long-Acting Beta2-Agonist (LABA): Potential risk of uncommon, severe, life threatening or fatal exacerbation. Not to be used to treat acute symptoms or exacerbations. Should not be used as monotherapy for long-term control of asthma or as anti-inflammatory therapy. May provide more effective symptom control when added to standard doses of ICS compared to increasing the ICS dosage. See full EPR-3 for additional discussion regarding safety of LABAs. FDA warning on all LABAs. To access the complete FDA Safety Announcement go to: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200776.htm

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