

# The Medical Letter<sup>®</sup>

## On Drugs and Therapeutics

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### IN BRIEF

#### Stopping Long-Acting Beta-2 Agonists

A little more than a year ago, The Medical Letter reported the results of an FDA meta-analysis which found that use of a long-acting beta-2 agonist (LABA) such as salmeterol (*Severent*) or formoterol (*Foradil*) in patients with asthma was associated with an increased risk of a composite endpoint of asthma-related death, intubation or hospitalization; the highest risk was in children 4-11 years old. There was no significant increase in risk when a long-acting beta-2 agonist was used with an inhaled corticosteroid. The Medical Letter recommended that long-acting beta-2 agonists should not be used as monotherapy for asthma, especially in children, and that long-acting beta-2 agonists should be used for asthma only in combination with an inhaled corticosteroid, preferably in a fixed-dose combination in the same inhaler.<sup>1</sup>

Now the FDA has issued new Safe Use Requirements<sup>2</sup> and labeling requirements for long-acting beta-2 agonists that include the following: "Stop use of the LABA, if possible, once asthma control is achieved and maintain the use of an asthma-controller medication such as an inhaled corticosteroid."<sup>3</sup>

It has not been determined that patients taking a long-acting beta-2 agonist in a fixed-dose combination with an inhaled corticosteroid have an increased risk of death or that stopping long-acting beta-2 agonists in such patients will improve long-term outcomes. A controlled clinical trial of these new requirements would be welcome. □

1. Long-acting beta-2 agonists in asthma. *Med Lett Drugs Ther* 2009; 51:1.
2. [www.fda.gov/safety/medwatch/default.htm](http://www.fda.gov/safety/medwatch/default.htm)
3. BA Chowdhury and G Dal Pan. The FDA and safe use of long-acting beta-agonists in the treatment of asthma. *N Engl J Med* 2010; Feb 24 (epub).

**Table 1. Some Drugs for Asthma**

Drug	Formulations	Adult Dosage	Pediatric Dosage	Cost <sup>1</sup>
<b>Inhaled Corticosteroid/Long-Acting Beta-2 Agonist Combinations</b>				
Budesonide/formoterol <i>Symbicort HFA</i> (AstraZeneca)	MDI (120 inh/unit) 80, 160 mcg/4.5 mcg/inh	2 inh bid	≥ 12 yrs: 2 inh bid	\$185.10
Fluticasone/salmeterol <i>Advair Diskus</i> (GSK)	DPI (60 inh/unit) 100, 250, 500 mcg/ 50 mcg/blister	1 inh bid	4-11 yrs: 1 inh (100/50 mcg) bid	175.99
<i>Advair HFA</i> (GSK)	MDI (120 inh/unit) 45, 115, 230 mcg/ 21 mcg/inh	2 inh bid	≥ 12 yrs: 2 inh bid	187.95
<b>Some Inhaled Corticosteroids</b>				
Budesonide <i>Pulmicort Flexhaler</i> (AstraZeneca)	DPI (60, 120 inh/unit) 90, 180 mcg/inh	360-720 mcg bid	6-17 yrs: 180-360 mcg bid	151.75
Fluticasone propionate <i>Flovent Diskus</i> (GSK)	DPI (60 inh/unit) 50 mcg/blister	100-500 mcg bid	4-11 yrs: 50-100 mcg bid	209.48
<i>Flovent HFA</i> (GSK)	HFA MDI (120 inh/unit) 44, 110 or 220 mcg/inh	88-440 mcg bid	4-11 yrs: 88 mcg bid	109.19

DPI = Dry powder inhaler; inh = inhalation; MDI = Metered-dose inhaler

1. Cost based on 30 days' treatment with the lowest recommended adult dosage based on prices at drugstore.com accessed March 15, 2010.

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