

Advair FDA Warning Fact Sheet

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The FDA has issued a statement suggesting Advair may not be first choice treatment for some patients with asthma. These are the facts surrounding their recommendation:

1. Advair contains two ingredients, fluticasone (Flovent) and salmeterol (Serevent).
2. A single research study, commonly referred to as the SMART study (in which I participated), prompted the concerns that have been in the media over the last 3 years.
3. The SMART study was done on Serevent, NOT Advair, and, in fact, Advair was not on the market when the study began.
4. The study showed a small but significant increased risk of death from an asthma attack in those using Serevent, especially among African-Americans.
5. Patients in the study who were also using an inhaled steroid, like fluticasone, that is an ingredient in Advair, were at no increased risk of death from an asthma attack, and the risk of other severe respiratory events was decreased.
6. Even patients who were treated with the wrong medications, but were being cared for by their own doctor, and not a "study center" doctor, were at no increased risk of death.
7. The study confirmed a long held belief that Serevent should not be used unless combined with a steroid inhaler.
8. The Serevent in Advair cannot be used independently from the steroid part of the inhaler (Flovent).

The facts as to why many experts believe the FDA's concerns are not warranted:

1. Routine use of a steroid inhaler is the cornerstone of asthma treatment in almost all patients with asthma.
2. About two-dozen studies have been completed showing adding a medication like Serevent to a steroid inhaler was more effective than doubling the dose of the steroid.
3. Studies show that patients are twice as likely to use Advair compared to a single ingredient steroid inhaler (perhaps because it is easier to use).
4. Many steroid inhalers must be used with expensive, cumbersome, spacers to be used properly, decreasing the chance medicines actually reach the lungs.
5. Based on public information, no new data has become available to the FDA since the first warning was issued in 2003; it is unlikely that new information will ever be available, only new opinions about the existing data.
6. Most experts agree, in retrospect, that the SMART study was a poorly designed study; it is difficult to draw meaningful conclusions from this study.
7. As an independent thinker, it is not unusual for me to disagree with regulatory recommendations made by our well-intentioned federal government in an attempt to protect me from all possible risks I might face in life.

Your potential risks and benefits if you choose to discontinue Advair and begin another prevention inhaler:

1. The need for an increased dose of steroid in your inhaler.
2. An increased risk of an asthma attack.

3. Decreased chance you (or your child) will actually use the medicine properly.
4. Theoretic decreased risk of a catastrophic asthma outcome.

The FDA agrees that no one should stop his or her asthma medications suddenly. The FDA agrees that many patients' asthma is significant enough to warrant using Advair as a first choice. If you desire to discuss changing your medications, schedule an appointment. This is too important a decision to handle over the phone.