

Safety Concerns Halt Asthma Drug Study

Users of Popular Asthma Drug Serevent Need Steroids, Too

If you're taking the asthma drug Serevent, talk to your doctor. You should be taking a corticosteroid, too. The drug's maker, GlaxoSmithKline, has halted a safety study of the drug, the FDA announced today. The reason: increased asthma deaths and serious asthma attacks among those taking Serevent without an inhaled corticosteroid -- especially among African-Americans. While just small numbers of patients had these complications, "they are troublesome," Laura Bradbard, FDA spokeswoman, tells WebMD. However, both GlaxoSmithLine (GSK) and the FDA urge patients not to quit taking Serevent or any asthma control medication without first checking with your doctor. Abruptly stopping medications may result in a severe asthma attack, they say. Today's announcement, although backed by only preliminary results, says that African-American patients (17% of the study population) on Serevent had a significantly greater number of respiratory and asthma-related events -- including deaths -- than those taking placebo plus an inhaled corticosteroid to reduce inflammation. However, only 1% of all African-Americans enrolled in the study experienced these events in the 28-week trial. But the key seems to be whether or not someone was taking inhaled corticosteroids, which reduce inflammation. The increased asthma deaths were seen only among people who were on Serevent but not on corticosteroids, too. Among patients on both types of drugs, there was no increased risk of problems compared to placebo. Whether or not a patient used inhaled corticosteroids was determined by their doctor, not by the study design, according to a GSK news release. Only half of the white patients and 38% of African-American patients were receiving treatment with inhaled corticosteroids. While corticosteroids reduce inflammation, Serevent and other drugs in the same class called beta-2-agonists help prevent airway spasms -- "when the airways tighten and narrow, causing difficulty in airflow," Lisa Behrens, GSK spokeswoman, tells WebMD. "Both are necessary to prevent a very life-threatening problem." In fact, the National Asthma Education and Prevention Program guidelines recommend that patients requiring more than "as-needed" asthma control inhalers should be prescribed regular and adequate doses of an inhaled anti-inflammatory asthma medication, such as inhaled corticosteroids, for optimal asthma management, says Behrens. "We don't know why there was this pattern, and would like to do further studies," says Bradbard. "Is it a socioeconomic reason? Is there a problem getting to the doctor often enough? Is the doctor following the guidelines? Or is there a physiological reason why African-Americans have more asthma? It does seem that population suffers from more asthma, and it tends to be more severe. Is it because it's not being treated, or because it's being treated too late? There are too many questions. That's why we need more studies." The company and the FDA are discussing future studies to provide more information about the appropriate use of Serevent in patients with asthma, particularly African-Americans.

Additionally, GSK and the FDA agree that:

- Serevent is not a replacement for inhaled corticosteroids, which should be continued at the same dose, and not stopped or reduced, when treatment of Serevent is initiated.
- Serevent should not be initiated in patients with significantly worsening asthma, which may be life threatening.
- Serevent should not be used to treat acute symptoms.
- Patients on Serevent must have a short-acting inhaler to open up airways (called a bronchodilator -- like albuterol) for use as needed for acute symptoms.
- Needing the short-acting bronchodilator more frequently is a sign of deteriorating asthma.
- Patients should be educated to recognize the signs of deteriorating asthma control and the need to seek medical attention promptly in such circumstances.