

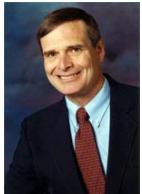


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Long Acting Bronchodilators

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September 2008

The US Food and Drug Administration (FDA) Advisory Panel has issued a Black Box Warning Alert regarding use of long-acting bronchodilators found in Advair, Serevent, and Foradil.

Rare (sometimes fatal) asthma-related problems have occurred in patients being treated for asthma with long-acting bronchodilators (LABAs). In patients taking LABAs for 28 weeks, there were 13 deaths in 13,176 patients (0.08% or 8/10,000) versus the placebo group with 3 deaths in 13,179 (0.03% or 3/10,000). The majority of these deaths occurred in African-American patients. Whether the risk in African-Americans is due to factors such as a physiologic effect, genetic factors, or patient behavior leading to poor outcomes (e.g. delay in seeking care or noncompliance) remains unknown. Review of the study could not establish a direct causal relationship associated with use of these drugs per sé, but did raise a concern regarding the importance of using these drugs strictly as prescribed. This is not unique to LABAs. Asthma can also worsen when overusing rescue inhalers such as albuterol.

It is important to recognize that there are a very small number of patients who may notice an increase in their asthma symptoms when taking a LABAs. This generally occurs in the first weeks of treatment and resolves when the medication is stopped.

The FDA has requested that a “black box” warning be placed on these medications to alert the public about these findings and to encourage patients to discuss the proper use of these drugs with their doctors. It is worth noting that the FDA Advisory Committee affirmed that these drugs should remain on the market because, in general, their benefits are felt to far outweigh the risks.

CAAC providers follow FDA guidelines for LABAs which include the following suggestions:

- LABAs should not be the first medicine used to treat asthma. LABAs should be added if other medications are not controlling asthma.
- Use LABAs in conjunction with an inhaled steroid. LABAs should never be used alone as a controller medication for asthma.
- Patients who are currently taking LABAs should not discontinue their treatment without first consulting a physician. Abruptly stopping medications may result in acute loss of asthma control, which may be lifethreatening.
- LABAs should not be used to treat acute symptoms.
- Patients on LABAs must also have a short-acting bronchodilator (e.g., albuterol) for treating acute symptoms.
- Patients need to recognize that increased need for using a short-acting bronchodilator is a sign of deteriorating asthma (e.g. use of albuterol more than 4 times in 24 hours).
- Patients experiencing increased asthma should seek medical attention promptly.

Do not stop your asthma medication without consulting your physician. Untreated asthma poses a much greater risk than using LABAs. We encourage you to discuss any concerns that you may have regarding the use of LABAs with your provider.