Black Box Warning Removed From Asthma Medications

FDA Removes Black Box Warning on Asthma Medications

Patients taking Breo, Advair, Symbicort, Dulera & AirDuo Can Breathe Easier

The Food and Drug Administration (FDA) has recently announced the removal of the Black Box Warning for asthma medications containing both inhaled steroids (ICS) and long-acting bronchodilators (LABA). Specifically, the following label will be removed from products including Breo, Advair, Symbicort, Dulera, AirDuo, and the generic product salmeterol/fluticasone.

“Black Box Warning” for Asthma Medications – The Back Story:

A “Black Box Warning” is the most severe FDA warning of serious hazards for medications and is found on the medication’s labeling and/or packaging insert.
Coupons for asthma medication including Advair, AirDuo, Breo, Dulera & Symbicort

In 2003, the safety of ICS/LABA products was called into question after the analysis of an asthma study called Salmeterol Multicenter Asthma Research Trial (SMART.) The SMART study showed a statistically significant increased risk of asthma-related deaths in patients on salmeterol (LABA.) At that time, the FDA mandated label changes in all products containing LABAs used for asthma but not COPD. The allergists at The Asthma Center and other asthma specialists have known for years that LABA when used in combination with ICS did not lead to increased risk of asthma-related deaths, but LABAs alone, without inhaled steroids, were still of concern. Further vigorous research studies, including those done at The Asthma Center, have shown that the risk of serious asthma-related events was no greater with ICS/LABAs than with ICS alone and that there was a low number of hospitalizations and no asthma-related deaths occurring in the ICS/LABA combinations. Consequently, the FDA has announced formally that there is no risk for asthma-related deaths, and the “black box warning” has now been removed from ICS/LABA combinations. We applaud the FDA for catching up with the clinical data that has been known for years in regard to safety of ICS/LABAs and that this should give more comfort to patients who are using these products on a chronic basis.
How The Asthma Center Can Help

The board-certified asthma specialists at The Asthma Center are the Delaware Valley’s leading experts on treating patients with asthma. With advanced in-office diagnostics, our asthma specialists are trained to correctly diagnosis and treat asthma symptoms and flares. Working with each patient individually, our allergists create a personalized asthma treatment plan to prevent and treat asthma. The board-certified asthma specialists at The Asthma Center treat patients in 9 convenient locations throughout the Delaware Valley.

Call now to schedule your appointment!

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For questions regarding the removal of the black box warning for ICS/LABA medications, please email Gaille at gwoodlyn@asthmacenter.com. The health information contained in this article is meant for basic informational purposes only. It is not intended to serve as medical advice, substitute for a doctor’s appointment or to be used for diagnosing or treating a disease.