

Transcript Details

This is a transcript of an educational program accessible on the ReachMD network. Details about the program and additional media formats for the program are accessible by visiting: <https://reachmd.com/programs/FDA-Drug-Information-Updates/fda-review-adding-labas-ics-treatment-does-not-significantly-increase-serious-asthma-outcomes-risk/9950/>

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FDA Review: Adding LABAs to ICS Treatment Does Not Significantly Increase Serious Asthma Outcomes Risk

Welcome to the FDA Drug Safety Podcast for health care professionals from the Division of Drug Information. This is Lesley Navin, Advanced Practice Nurse.

On December 20, 2017, FDA announced that a review of four large clinical safety trials shows that treating asthma with long-acting beta agonists (LABAs) in combination with inhaled corticosteroids (ICS) does not result in significantly more serious asthma-related side effects than treatment with ICS alone. In 2011, we required the drug companies that market LABAs to conduct these trials to evaluate the safety of LABAs when used in combination with ICS.

The *Boxed Warning*, our most prominent warning, about asthma-related death has been removed from the drug labels of medicines that contain both an ICS and LABA. A description of the four trials is now included in the *Warnings and Precautions* section of the drug labels for combination ICS and LABA medicines. These trials showed that LABAs, when used with ICS, did not significantly increase the risk of asthma-related hospitalizations, intubation, or asthma-related deaths, compared to ICS alone.

Using LABAs alone to treat asthma without an ICS to treat lung inflammation is associated with an increased risk of asthma-related death. Therefore, the *Boxed Warning* stating this will remain in the labels of all single-ingredient LABA medicines, which are approved to treat asthma, chronic obstructive pulmonary disease (COPD), and wheezing caused by exercise. The labels of medicines that contain both an ICS and LABA also retain a *Warning and Precaution* related to the increased risk of asthma-related death when LABAs are used without an ICS to treat asthma.

Medicines that contain both an ICS and LABA are FDA-approved to treat both asthma and COPD. ICS medicines help decrease inflammation in the lungs which can lead to breathing problems. LABAs help the muscles around the airways in the lungs stay relaxed to prevent symptoms such as wheezing, coughing, chest tightness, and shortness of breath. Combination ICS and LABA medicines are marketed under several brand names, including Advair, Airduo, Breo, Dulera, and Symbicort.

Health care professionals should refer to the most recently approved drug labels for recommendations on using combination ICS and LABA medicines

Report side effects involving combination ICS and LABAs to FDA's MedWatch program at www.fda.gov/medwatch.

A link to the full communication detailing information for health care professionals and the Data Summary can be found at www.fda.gov/DrugSafetyCommunications. If you have drug questions, you can reach us at druginfo@fda.hhs.gov

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