

## I've been hearing about asthma medicines in the news. What's going on?

- On December 10 and 11, 2008, an Advisory Committee to the US Food and Drug Administration (FDA) reviewed safety data from a class of medicines known as long-acting beta<sub>2</sub>-agonists, or LABAs. The purpose of this meeting was to assess the benefits and risks of these medicines in children and adults with asthma. This review included all LABAs and LABA-containing products, including:
  - SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder)
  - ADVAIR DISKUS® (fluticasone propionate and salmeterol inhalation powder)
  - Symbicort® (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol
  - Foradil® (formoterol fumarate inhalation powder)
  - ADVAIR® HFA (fluticasone propionate and salmeterol) Inhalation Aerosol
- LABAs are long-acting bronchodilator medicines. They are daily controller medicines that relieve and help prevent airway constriction. Airway constriction is one of the two main components of asthma. LABAs do not treat the other main component of asthma – inflammation. Inflammation is treated by another type of daily controller medicine called an inhaled corticosteroid (ICS). LABAs, including SEREVENT, should not be used alone in the treatment of persistent asthma. National treatment guidelines recommend that LABAs be used only in combination with an ICS.

## What is ADVAIR® (fluticasone propionate and salmeterol)? Is it a LABA?

- ADVAIR is a *combination therapy*, which means it contains two medicines – a LABA (salmeterol) and an ICS (fluticasone propionate). Together, these daily preventative medicines treat both of the main components of asthma – airway constriction and inflammation.
- The use of *combination therapy* is supported by the National Institutes of Health (NIH) Guidelines for the Diagnosis and Management of Asthma. The guidelines recommend *combination therapy* with an ICS and a LABA as a preferred daily preventative treatment for patients 5 years of age and older whose asthma is not well controlled on an ICS alone, or for patients 12 years and older with moderate to severe persistent asthma.
- ADVAIR DISKUS was approved by the FDA in 2000 for the treatment of asthma and has been studied in more than 30 US clinical studies involving more than 14,300 patients with asthma.
- Since 2000, there have been more than 106 million prescriptions of ADVAIR dispensed in the United States. Clinical studies demonstrate that ADVAIR is very effective in reducing and helping to prevent asthma symptoms, reducing the use of albuterol (fast-acting or rescue) inhalers, and improving lung function.

## What happened in the FDA Advisory Committee meeting?

- The Advisory Committee was asked to evaluate the risks and benefits of several products, including SEREVENT and ADVAIR, for adults, adolescents, and children with asthma. The Advisory Committee makes recommendations to the FDA, which then makes the final decision on any actions required.
- For ADVAIR, the Committee unanimously voted that the benefits of ADVAIR outweigh the risks for patients 18 years and older. The Committee also voted in favor of ADVAIR for patients 12 to 17 years of age and patients 4 to 11 years of age, although the votes for these age groups were not unanimous.
- For SEREVENT, the Committee found that the benefits do not outweigh the risks for the treatment of asthma, based on the current Prescribing Information.

## Why are the recommendations for SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder) not the same as for ADVAIR? Isn't SEREVENT part of ADVAIR?

- There are two main components of asthma – airway constriction and inflammation. SEREVENT treats the airway constriction, but not the inflammation. SEREVENT is not approved to be used without another controller medicine for the treatment of asthma because of the risk of serious asthma-related events, including asthma-related death.
- The Advisory Committee recognized that despite the Prescribing Information stating that SEREVENT should not be used without another asthma controller medicine, the potential remained for SEREVENT to be used alone.
- While SEREVENT (salmeterol) is part of ADVAIR, ADVAIR is a combination therapy, which means it contains two medicines, a LABA (salmeterol) and an ICS (fluticasone). Together, these medicines ensure that both of the main components of asthma – airway constriction and inflammation – are being treated.
- The Advisory Committee continued to support the use of combination therapy, such as ADVAIR, in the treatment of moderate to severe persistent asthma.

## Has ADVAIR been recalled? Has it been taken off the market?

- No. ADVAIR has not been recalled or taken off the market. ADVAIR is effective for the treatment of asthma, and has a favorable safety profile when used according to the Prescribing Information. ADVAIR – unlike SEREVENT, which is a single medicine – contains two medicines in one device to treat both of the main components of asthma, inflammation and airway constriction.

### Important Information About ADVAIR 100/50, 250/50, 500/50 and ADVAIR HFA 45/21, 115/21, 230/21 for Asthma

**Prescription ADVAIR won't replace fast-acting inhalers for sudden symptoms and should not be taken more than twice a day.** ADVAIR is for people who still have symptoms on another asthma controller, or who need two controllers. ADVAIR contains salmeterol. In patients with asthma, medicines like salmeterol may increase the chance of asthma-related death. So ADVAIR is not for people whose asthma is well controlled on another controller medicine.

Talk to the doctor about the risks and benefits of treating asthma with ADVAIR. Do not use ADVAIR with long-acting beta<sub>2</sub>-agonists for any reason. If taking ADVAIR, see the doctor if asthma does not improve or gets worse. Thrush in the mouth and throat may occur. Tell the doctor about any heart condition or high blood pressure. Some people may experience increased blood pressure, heart rate, or changes in heart rhythm. Inhaled corticosteroids as well as poorly controlled asthma may cause a reduction in growth rate. The long-term effect on final adult height is unknown.

ADVAIR DISKUS is for patients 4 years and older. For patients 4 to 11 years old, ADVAIR DISKUS 100/50 is for those who have asthma symptoms while on an inhaled corticosteroid. ADVAIR HFA is for patients 12 years and older.

### Important Information About SEREVENT DISKUS

**SEREVENT DISKUS does not replace fast-acting inhalers for sudden symptoms and should not be taken more than twice a day.**

Please see accompanying complete Prescribing Information and Medication Guides for [ADVAIR DISKUS](#), [ADVAIR HFA](#), and [SEREVENT DISKUS](#) to obtain important information.

## Is ADVAIR® safe? Should I or my child continue taking ADVAIR for asthma?

- ADVAIR is a very effective medication for persistent asthma and has a favorable safety profile when used according to the Prescribing Information. ADVAIR DISKUS continues to be approved for the treatment of asthma in people 4 years of age and older. You should talk to your healthcare provider if you have any questions or concerns about ADVAIR or any other asthma medicine you are taking. Do not stop taking or change your asthma medicine without talking to the doctor first. Stopping your asthma medicine could lead to uncontrolled asthma, putting you at risk for increased asthma symptoms or sudden attacks, which in some cases could lead to hospitalizations, or even death. Your healthcare provider can assess your asthma and decide whether a change in treatment is appropriate.

## Has SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder) been taken off the market? Has it been recalled?

- No. SEREVENT has not been recalled or taken off the market. The FDA will evaluate the recommendations of the Advisory Committee and decide how or if SEREVENT should remain available for the treatment of asthma. Please talk to your doctor if you have any questions or concerns about SEREVENT.

## Should I or my child continue taking SEREVENT for asthma?

- Do not stop taking asthma medicines without talking to the doctor. You should talk to the doctor if you have any questions or concerns about your asthma treatment or your child's asthma treatment.

## I take ADVAIR DISKUS 250/50 or SEREVENT for COPD (Chronic Bronchitis or Emphysema). Should I continue taking ADVAIR or SEREVENT for my COPD?

- The FDA Advisory Committee review focused on the use of LABAs and LABA-containing products (for example, SEREVENT and ADVAIR, respectively) in the treatment of childhood and adult asthma ONLY. Both ADVAIR and SEREVENT continue to also be approved for the treatment of COPD. If you have any questions about your COPD treatment, talk to your doctor.

## What happens next?

- The FDA will take the Committee's recommendations under consideration and will make decisions as soon as possible. GSK will fully comply with any decision by the FDA regarding its products. GSK is committed to patient safety.

## Where can I get more information about asthma and ADVAIR?

- Visit [asthma.com](http://asthma.com) or [ADVAIR.com](http://ADVAIR.com) for more information or call the GlaxoSmithKline Response Center at 1-888-825-5249.

### Important Information About ADVAIR DISKUS 250/50 for COPD (Chronic Bronchitis or Emphysema)

ADVAIR DISKUS 250/50 is approved for adults with COPD, including chronic bronchitis, emphysema, or both. You should only take 1 inhalation of ADVAIR twice a day. Higher doses will not provide additional benefits. People with COPD taking ADVAIR may have a higher chance of pneumonia. Call your doctor if you notice any of the following symptoms: change in amount or color of sputum, fever, chills, increased cough, or increased breathing problems. ADVAIR may increase your risk of osteoporosis and some eye problems (cataracts or glaucoma). You should have regular eye exams. Thrush in the mouth and throat may occur. Tell your doctor if you have a heart condition or high blood pressure before taking ADVAIR. Do not use ADVAIR with long-acting beta<sub>2</sub>-agonists for any reason. ADVAIR does not replace fast-acting inhalers for sudden symptoms.

### Important Information About ADVAIR for Asthma

ADVAIR won't replace fast-acting inhalers for sudden symptoms and should not be taken more than twice a day.

### Important Information About SEREVENT DISKUS

In patients with asthma, medicines like SEREVENT may increase the chance of asthma-related death. Talk to your doctor about this risk and the benefits of treating your asthma with SEREVENT. SEREVENT should not be the only controller medicine prescribed for your asthma and is not a substitute for anti-inflammatory medications (inhaled or oral corticosteroids). Tell your doctor if you have a heart condition or high blood pressure. Some people may experience increased blood pressure, heart rate, or changes in heart rhythm. See your doctor if your asthma does not improve.

SEREVENT DISKUS is indicated for long-term, twice-daily (morning and evening) administration in the maintenance treatment of asthma in patients 4 years of age and older. SEREVENT DISKUS is also indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

SEREVENT DISKUS is indicated for the long-term, twice-daily (morning and evening) administration in the maintenance treatment of bronchospasm associated with COPD (including emphysema and chronic bronchitis).

While you are using SEREVENT DISKUS, ADVAIR DISKUS, or ADVAIR HFA twice a day, do not use other medicines that contain a long-acting beta<sub>2</sub>-agonist or LABA for any reason. Other LABA medicines include FORADIL® AEROLIZER® (formoterol fumarate inhalation powder), SYMBICORT® (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol, PERFOROMIST™ (formoterol fumarate) Inhalation Solution, and BROVANA™ (aformoterol tartrate) Inhalation Solution.

The brands listed, with the exception of ADVAIR, ADVAIR DISKUS, SEREVENT, and DISKUS, are trademarks or registered trademarks of their respective owners and are not trademarks of The GlaxoSmithKline Group of Companies. The makers of these brands are not affiliated with and do not endorse GlaxoSmithKline or its products.

Please see accompanying complete Prescribing Information and Medication Guides for [ADVAIR DISKUS](#), [ADVAIR HFA](#), and [SEREVENT DISKUS](#) to obtain important information.

**ADVAIR DISKUS**<sup>®</sup> 100/50, 250/50, 500/50  
(fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder)

**ADVAIR HFA** 45/21, 115/21, 230/21  
(fluticasone propionate 45, 115, 230 mcg and salmeterol 21 mcg) Inhalation Aerosol