

Important Drug Warning About SEREVENT® DISKUS

On Monday, January 10, 2011, GlaxoSmithKline began mailing a letter to healthcare professionals that informed them of important safety information for SEREVENT® DISKUS® (salmeterol xinafoate inhalation powder) in the treatment of asthma. The healthcare professionals who will receive the letter are potentially members of your society. Additionally, we are asking you to share this communication (including all attachments) with members of your society and advice practitioners prescribing SEREVENT DISKUS to discuss the benefits and risks of LABAs with their patients to assure appropriate distribution of this important information. They should also encourage each patient prescribed SEREVENT DISKUS to thoroughly review the enclosed Medication Guide prior to using.

Important safety information related to SEREVENT DISKUS includes:

- Increased risk of asthma-related death in patients taking LABAs.
- New prescribing guidelines.
 - SEREVENT DISKUS should only be used as concomitant therapy with a long-term asthma control medication, such as an inhaled corticosteroid (ICS), in patients aged 4 years and older with reversible obstructive airway disease.
 - Use of SEREVENT DISKUS for the treatment of asthma without concomitant use of a long-term asthma control medication, such as an ICS, is contraindicated.
 - Use of SEREVENT DISKUS only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on a long-term asthma control medication, such as an ICS.
 - Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue SEREVENT DISKUS) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an ICS.
 - Do not use SEREVENT DISKUS for patients whose asthma is adequately controlled on low- or medium-dose ICS.
 - For pediatric and adolescent patients with asthma who require addition of a LABA to an ICS, a fixed-dose combination product containing both an ICS and a LABA should ordinarily be used to ensure adherence with both drugs. In cases where use of a separate long-term asthma control medication (e.g., ICS) and a LABA is clinically indicated, appropriate steps must be taken to ensure adherence with both treatment components. If adherence cannot be assured, a fixed-dose combination product containing both an ICS and a LABA is recommended.

SEREVENT DISKUS is a long-acting beta2-adrenergic agonist (LABA) indicated for the treatment of asthma in the prevention of bronchospasm only as concomitant therapy with a long-term asthma control medication, such as an inhaled corticosteroid (ICS), in patients aged 4 years and older with reversible obstructive airway disease, including patients with symptoms of nocturnal asthma. SEREVENT DISKUS is not indicated for the relief of acute bronchospasm.

Please take the time to read the enclosed SEREVENT DISKUS Package Insert for full prescribing information for complete description of this important safety information and the new prescribing guidelines. You can also visit www.serevent.com for additional information about the risk of serious asthma outcomes and the safe use of LABAs.

Please contact GlaxoSmithKline at 1-888-825-5249 if you have any questions about SEREVENT DISKUS or the information in this letter.