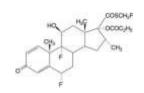
(100 % EXPORT QUALITY MEDICINE







GENERIC NAME: fluticasone propionate and salmeterol oral inhaler

DRUG CLASS AND MECHANISM

Advair Diskus is a combination of inhaled drugs that is used to treat asthma and chronic bronchitis. In patients with asthma, the airways (bronchioles) through which air moves in and out of the lungs can be narrowed by accumulation of mucus, spasm of the muscles that surround these airways, or swelling of the lining of the airways due to inflammation. Airway narrowing leads to symptoms of shortness of breath, wheezing, cough, and congestion. Medications used in treating asthma include those that open airways, called bronchodilators, and those that reduce inflammation.

Advair Diskus contains a combination of salmeterol, a bronchodilator of the beta-2 agonist type, and fluticasone propionate, an anti-inflammatory corticosteroid. Beta-2 agonists are medications that attach to beta-2 receptors on the smooth muscle cells that surround the airways, causing the muscle cells to relax and open the airways. Fluticasone propionate is a synthetic (man-made) corticosteroid of the glucocorticoid family which is related to the natural hormone, cortisol or hydrocortisone, produced by the adrenal glands. Glucocorticoid steroids have potent anti-inflammatory actions. In asthmatic patients, the suppression of inflammation within the airways reduces the swelling caused by inflammation that narrows the airways. At the same time, mucus is reduced. When used in lower doses, very little inhaled fluticasone propionate is absorbed into the body. When higher doses are used, fluticasone is absorbed and may cause side effects elsewhere in the body.

PRESCRIPTION: Yes

GENERIC AVAILABLE: No

PREPARATIONS

Advair Diskus is available in three different forms containing the same amount of salmeterol, 50 mcg, but differing in the amount of fluticasone propionate. 100/50 provides 100 mcg of fluticasone propionate, 250/50 provides 250 mcg of fluticasone propionate, and 500/50 contains 500 mcg of fluticasone propionate per inspiration.

PRESCRIBED FOR

Advair Diskus is used for the treatment of asthma or chronic obstructive pulmonary disease **(COPD)** associated with chronic bronchitis. Its action starts within 30 to 60 minutes and can last more than 12 hours. Advair Diskus is generally not needed in patients whose asthma can be controlled easily with infrequent administration of short acting inhalers. Advair Diskus should not be used to treat acute episodes of asthma or **COPD**.

DOSING

The recommended regimen for asthma in individuals 12 years and older is one inhalation twice daily (morning and evening) approximately 12 hours apart. The lowest effective strength should be used and the maximum dose is 500/50 mcg twice daily. For children 4 to 11 years old the recommended treatment is one inhalation of 100/50 mcg twice daily.

The recommended regimen for ${\bf COPD}$ is one inhalation of 250/50 mcg twice daily. Higher doses are not more effective.

The Diskus device is held in one hand with the thumb of the other hand placed on the thumb-grip. The thumb is then pulled away as far as the device allows until the mouthpiece seems to click into position. With the Diskus then held horizontally and with the mouthpiece towards the patient, the lever is then slid away as far as it can go until it clicks. The patient breathes out as far as comfortable, then placing his mouth to the mouthpiece, breathes in quickly and deeply and holds his breath for about ten seconds. The patient then washes his or her mouth without swallowing after inhalation.

DRUG INTERACTIONS

Monoamine oxidase inhibitors (for example, tranylcypromine) and tricyclic

antidepressants (for example, amitriptyline (Endep)] may increase the effect of salmeterol on the heart and blood pressure. Since Advair Diskus contains salmeterol, it should not be used with or within two weeks of discontinuing monoamine oxidase inhibitors or tricyclic antidepressants.

PREGNANCY

Adequate studies of fluticasone or inhaled salmeterol during pregnancy have not been done. Fluticasone use during pregnancy should be avoided unless the potential benefit justifies the potential but unknown risk to the fetus. In some, but not all, pregnant animal models exposure to very high doses of oral salmeterol has led to offspring with birth defects. The concentrations of salmeterol in the blood after these very high doses, however, were much higher than the concentrations observed after inhalation. Salmeterol inhalation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

SIDE EFFECTS

Upper respiratory tract infections occur in 20%-25% of patients using Advair Diskus. Headaches occur in about 1 in 8 patients who use it. Other potential adverse events include nausea, vomiting, diarrhea, mouth or throat candidiasis, and musculoskeletal pain. Use of long acting agents like salmeterol, an active ingredient in Advair Diskus, may increase the risk of asthma-related death. Therefore Advair Diskus should only be used in patients uncontrolled by other agents.

STORAGE

Advair Diskus should be stored at 36-86 F (2.2-30 C). It should be kept away from heat or flames and should not be punctured; it should not be frozen or placed in direct sunlight.



Taj Group of Companies INDIA

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91, (0)22 - 26374592/93 91 - (0)22 - 30601000,

Fax: 91-(0)22-26341274

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