AirFluSal® BSS [1]

AirFluSal® Forspiro® 50/500 Salmeterol + Fluticasone Propionate Pre-dispensed powder for oral inhalation. AirFluSal® Forspiro® 50/250 Salmeterol + Fluticasone Propionate Pre-dispensed powder for oral inhalation. Each metered dose of AirFluSal® Forspiro® provides for 50 microgram/250 microgram/dose, inhalation powder, predispensed 50 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate. Corresponding with a delivered dose of 0.073 miligrams of Salmeterol Xinafoate and 250 micrograms of fluticasone propionate For 50 microgram/500 microgram/dose, inhalation powder, predispensed 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms of fluticasone propionate. Corresponding with a delivered dose of 0.073 miligrams of Salmeterol Xinafoate and 500 micrograms of fluticasone propionate. Excipient with known effect lactose monohydrate. Indications. Asthma. In the regular treatment of asthma where use of a combination product (long-acting beta-2-agonist and inhaled corticosteroid) is appropriate. Chronic Obstructive Pulmonary Disease (COPD). For the symptomatic treatment of patients with COPD, with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. Posology. Patients should be made aware that AirFluSal® Forspiro® must be used daily for optimum benefit, even when asymptomatic. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. Asthma. Adults and adolescents 12 years and older. One inhalation of 250 micrograms fluticasone propionate and 50 micrograms salmeterol twice daily or one inhalation of 500 micrograms fluticasone propionate and 50 micrograms salmeterol twice daily. A short term trial may be considered as initial maintenance therapy in adults or adolescents with moderate persistent asthma for whom rapid control of asthma is essential. COPD. Adults. One inhalation of 500 micrograms fluticasone propionate and 50 micrograms salmeterol twice daily. There is no need to adjust the dose in elderly patients or in those with renal impairment. There are no data available for use of AirFluSal® Forspiro® in patients with hepatic impairment. Asthma. AirFluSal® Forspiro® should not be used in children. COPD. AirFluSal® Forspiro® should not be used in children and adolescents. Contraindications. Hypersensitivity to the active substances or to any of the excipients. Precautions for use. Should not be used to treat acute asthma symptoms for which a fast and short acting bronchodilator is required. Patients should not be initiated on AirFluSal® Forspiro® during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur during treatment. Sudden and progressive deterioration in control of asthma is potentially life threatening and then patient should undergo urgent medical assessment. For patients with COPD experiencing exacerbations, treatment with systemic corticosteroids is typically indicated, therefore patients should be instructed to seek medical attention if symptoms deteriorate with AirFluSal® Forspiro®. Treatment with AirFluSal® Forspiro® should not be stopped abruptly in patients with asthma due to risk of exacerbation. As with all inhaled medication containing corticosteroids should be administered with caution in patients with pulmonary tuberculosis. May cause cardiac arrhythmias e.g. supraventricular tachycardia, extrasystoles and atrial fibrillation, and a mild transient reduction in serum potassium at high therapeutic doses. Should be used with caution in patients with severe cardiovascular disorders, heart rhythm abnormalities, diabetes mellitus, thyrotoxicosis, uncorrected hypokalaemia or patients predisposed to low levels of serum potassium. There have been very rare reports of increases in blood glucose levels. Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. Prolonged treatment of patients with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Ritonavir can greatly increase the concentration of fluticasone propionate in plasma. Physicians should remain vigilant for the possible development of pneumonia and other lower respiratory tract infections in patients with COPD as the clinical features of such infections and exacerbation frequently overlap. Data from a large clinical trial suggested African-American patients were at increased risk of serious respiratory-related events or deaths when using salmeterol compared with placebo.

Links
[1] https://www.sandozca.com/en/airflusal-bss