

Seraflo

HFA Inhaler
120 Puffs

Composition : Each metered dose (Puff) contains Salmeterol 25 mcg as Salmeterol Xinafoate and Fluticasone Propionate 250 mcg.

Indications : This Inhaler is indicated in the regular treatment of asthma where use of a combination product (long-acting beta-2-agonist and inhaled corticosteroid) is appropriate: Patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta-2-agonist or, Patients already adequately controlled on both inhaled corticosteroid and long-acting beta-2-agonist.

Dosage and administration : Adults and adolescents 12 years and older : Two inhalations of 25 micrograms salmeterol and 250 micrograms fluticasone propionate twice daily. Or as directed by the registered physician.

Side effects : Adverse events which have been associated with salmeterol or fluticasone propionate are given below. Salmeterol: The pharmacological side effects of beta- 2-agonist treatment, such as tremor, palpitations and headache, have been reported, transient and reduce with regular therapy. Cardiac arrhythmia may occur, usually in susceptible patients. Fluticasone Propionate: Hoarseness and candidiasis (thrush) of the mouth and throat can occur in some patients.

Contraindication : It is contraindicated in patients with a history of hypersensitivity to Salmeterol, Fluticasone or any other components of this product.

Use in pregnancy and lactation :

Administration of drugs during pregnancy and lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus or child. There is insufficient experience of the use of Salmeterol Xinafoate and Fluticasone Propionate in human pregnancy and lactation. There are no data available for human breast milk.

Drug interactions : Both non-selective and selective beta-blockers should be avoided in patients with asthma, unless there are compelling reasons for their use. Care should be taken when co-administering known strong CYP3A4 inhibitors(e.g.ketoconazole, ritonavir), as there is potential for increased systemic exposure to Fluticasone Propionate.

Precautions : Consideration should be given to additional corticosteroid therapies, and to including administration of antibiotics if an infection is present. This product should be administered with caution in patients with active or quiescent pulmonary tuberculosis, thyrotoxicosis.

Packing : Seraflo HFA Inhaler : Each box contains one inhaler of 120 Puffs.