

Seraflo

HFA Inhaler
60 & 120 Puffs

Salmeterol and
Fluticasone Propionate

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

Seraflo 25/125 HFA Inhaler: Each metered dose (Puff) contains Salmeterol 25 mcg as Salmeterol Xinafoate BP and Fluticasone Propionate BP 125 mcg.

Pharmacology : Fluticasone Propionate, a corticosteroid having the chemical name 5-(fluoromethyl) 6, 9-difluoro-11 β ,17-dihydroxy-16 α -methyl-3-oxoandrost-1,4-diene-17 β -carbothioate,17-propionate. Fluticasone Propionate is a white powder with a molecular weight of 500.6 and the empirical formula is C₂₅H₃₁F₃O₅S. It is practically insoluble in water, freely soluble in dimethyl sulfoxide and dimethylformamide, and slightly soluble in methanol and 95% ethanol. Salmeterol Xinafoate, a β -adrenergic bronchodilator. The chemical name of Salmeterol Xinafoate is 4-hydroxy- α 1-[[[6-(4-phenylbutoxy)hexyl]amino]methyl]-1,3-benzenedimethanol,1-hydroxy-2 naphthalenecarboxylate.

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, two inhalations of 25 micrograms salmeterol and 125 micrograms fluticasone propionate twice daily. Or, as directed by the registered physician.

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

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.

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.

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.

Use in child : Patient's using in child Should be strongly recommended to seek medical advice.

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.

Overdose: There are no data available from clinical trials on overdose with seraflo.

Storage: Store the medicine below 30° C in a dry place and avoid storage in direct sunlight or heat.

Packing: Seraflo HFA Inhaler: Each box contains one inhaler of 60 & 120 Puffs

Seraflo 25/125 HFA Inhaler: Each box contains one inhaler of 120 Puffs .

Manufactured by



DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh