# **SALFLU**

# Salmeterol (as Xinafoate) BP & Fluticasone Propionate BP

**HFA Inhalation Aerosol** 

FC FREE

#### DESCRIPTION

Salflu HFA Inhalation Aerosol is the combination of Salmeterol (as Xinafoate) & Fluticasone Propionate. It is a hydrofluoroalkane (HFA) based environment friendly inhaler. Because it does not contain chlorofluorocarbon (CFC) as propellant which is one of the main reasons of ozone layer depletion.

Salmeterol is a selective, long acting beta-2-agonist used in the treatment of asthma & other forms of diffuse airway obstruction. Fluticasone Propionate is a synthetic corticosteroid of glucocorticoid family, which have potent anti-inflammatory activity. Fluticasone Propionate is stated to exert topical effects on the lungs without systemic effects at usual dose.

## COMPOSITION

Salfflu 125: Each actuation delivers Salmeterol (as Xinafoate) BP 25 mcg & Fluticasone Propionate BP 125 mcg.

Salfilu 250: Each actuation delivers Salmeterol (as Xinafoate) BP 25 mcg & Fluticasone Propionate BP 250 mcg.

# INDICATIONS

- 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.
- Patients already adequately controlled on both inhaled corticosteroid and long-acting beta-2-agonist.

## DOSAGE AND ADMINISTRATION

	For asthma management and prophylaxis	
Age	Amount	Puffs
Adults including	Salmeterol 25 mcg and Fluticasone	2 puffs of SALFLU-125
elderly and	Propionate 125 mcg twice daily	twice daily
adolescents over	Salmeterol 25 mcg and Fluticasone	2 puffs of SALFLU-250
12 years of age	Propionate 250 mcg twice daily	twice daily

# OR AS DIRECTED BY THE PHYSICIAN.

## CONTRAINDICATIONS

**Salflu** is contraindicated in patients with the history of hypersensitivity to any of its ingredients.

#### SPECIAL PRECAUTIONS

Treatment with Salflu should not be stopped abruptly. Both non-selective and selective beta-blockers should be avoided in patients with asthma, unless there are compelling reasons for their use. As with all inhaled medication containing corticosteroids, Salflu should be administered with caution in patients with active or quiescent pulmonary tuberculosis. Salflu should be administered with caution in patients with severe thyrotoxicosis.

## PRECAUTION FOR PAEDIATRIC USE

Orally inhaled corticosteroids may cause a reduction in growth velocity when administered to paediatric patients. The long term effects of this

reduction including the impact of final adult height are unknown.

#### DRUG INTERACTION

Due to the very low plasma concentrations achieved after inhaled dosing, clinically significant drug interactions are unlikely.

#### **USE DURING PREGNANCY AND LACTATION**

There are insufficient experiences of the use of Salmeterol and Fluticasone Propionate in human 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 fetus or child.

#### SIDE EFFECTS

The pharmacological side effects of Salmeterol treatments such as tremor, subjective palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy. Cardiac arrhythmias may occur, usually in susceptible patients.

In case of Fluticasone Propionate, hoarseness and candidiasis (thrush) of the mouth and throat can occur in some patients. Gargling with water after use of **Salflu** HFA Inhalation Aerosol may relieve both hoarseness and incidence of candidiasis.

#### **OVERDOSE**

No data available from clinical trials on overdose with Salflu.

#### SUPPLY

Salfilu 125: Each canister contains 120 metered doses, each dose contains Salmeterol (as Xinafoate) BP 25 mcg & Fluticasone Propionate BP 125 mcg.

Salfilu 250: Each canister contains 120 metered doses, each dose contains Salmeterol (as Xinafoate) BP 25 mcg & Fluticasone Propionate BP 250 mcg.

#### **GENERAL PRECAUTIONS**

Do not puncture, break or incinerate the pressurised canister even when apparently empty.

Avoid storage in direct sunlight or heat.

Store in cool and dry place.

Keep away from children.

Keep away from eyes.

\* Further information is available on request.

FOR HEALTH, VIGOUR AND HAPPINESS



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