

Composition : **Seraflo 50/100 Mycap :** Each Capsule Contains Salmeterol 50mcg as Salmeterol Xinafoate BP and Fluticasone Propionate BP 100mcg inhalation powder.

Seraflo 50/250 Mycap : Each Capsule Contains Salmeterol 50mcg as Salmeterol Xinafoate BP and Fluticasone Propionate BP 250mcg inhalation powder.

Indications : Treatment of asthma : Fluticasone Propionate & Salmeterol Xinafoate combination is indicated for the treatment of asthma in patients aged 4 years and older. It is indicated for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. It is not indicated for the relief of acute bronchospasm.

Maintenance treatment of COPD : Fluticasone Propionate & Salmeterol Xinafoate combination is indicated for the maintenance treatment of airflow obstruction and to reduce exacerbations in patients with chronic obstructive pulmonary disease, including chronic bronchitis or emphysema.

Dosage and administration : Asthma

Adult and Adolescent (12 Years and Older) :

Seraflo 50/100 & Seraflo 50/250 Mycap : 1 Mycap capsule, twice daily (morning and evening, approximately 12 hours apart). The recommended starting dosages for **Seraflo 50/100 & Seraflo 50/250 Mycap** for patients aged 12 years and older are based upon patients' asthma severity.

Pediatric Patients (4 to 11 Years) :

For patients with asthma who are not controlled on an inhaled corticosteroid, the dosage is **Seraflo 50/100 Mycap :** 1 Mycap capsule, twice daily (morning and evening, approximately 12 hours apart).

Chronic obstructive pulmonary disease : Seraflo 50/250 Mycap: 1 Mycap capsule, twice daily (Morning and evening, approximately 12 hours apart). Or, as directed by the registered physician. Rinsing the mouth after each inhalation is advised.

Side effects : The most common side effects are oral candidiasis, pneumonia, immunosuppression hypercorticism, adrenal suppression, growth retardation, glaucoma and cataracts etc. Also the few side effects have been reported infrequently like ear signs and symptoms, nasal signs and symptoms, nasal sinus disorders, keratitis and

**Seraflo Mycap
Capsule**



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LTD.**

conjunctivitis, dental discomfort and pain, gastrointestinal signs and symptoms, oral ulcerations, oral discomfort and pain, lower respiratory signs and symptoms, muscle stiffness, tightness, and rigidity, bone and cartilage disorders, sleep disorders, compressed nerve syndromes, chest symptoms, fluid retention, unusual taste, viral skin infections, disorders of sweat and sebum.

Contraindication : It is contraindicated in patients with a hypersensitivity to Salmeterol Xinafoate or Fluticasone Propionate and any other components of this preparation. It is also contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma or COPD where intensive measures are required.

Use in Pregnancy and lactation : Pregnancy category C. There are no adequate and well controlled studies of this drug in pregnant woman. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when the drug is administered to a nursing mothers.

Drug Interaction : It should be used with caution when it is administered concomitant with CYP3A4 inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ketoconazole, telithromycin etc).

Precaution : This combination should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma or COPD and should not be used for the relief of acute bronchospasm and also Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract, untreated systemic fungal, bacterial, viral or parasitic infections, or ocular herpes simplex.

Overdose : There are no data available from Clinical trials on overdose with **Seraflo Mycap**.

Storage : Store below 30° C in a dry place. Protect from light & freezing. Insert the Mycap in the Myhaler just prior to use to protect from deterioration by moisture.

Packing : Seraflo 50/100 Mycap: Each box contains 3x10's capsules in Alu-Alu blister pack.

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