Information For the Use Salmeterol (50mcg) + Fluticasone Propionate (500 mcg)

Flutialfa SF 500 Capsule

Composition

Each dry powder capsule contains:

- Salmeterol (50 mcg): A long-acting beta-2 adrenergic agonist (LABA) that relaxes airway muscles, providing prolonged bronchodilation and preventing wheezing and breathlessness.
- Fluticasone Propionate (500 mcg): A potent inhaled corticosteroid (ICS) that reduces inflammation in the lungs, prevents airway swelling, and decreases mucus production.

Mechanism of Action

The combination of Salmeterol and Fluticasone Propionate provides **dual action** for better asthma and COPD control:

- Salmeterol binds to beta-2 adrenergic receptors in the lungs, causing relaxation of bronchial smooth muscles and preventing airway constriction for up to 12 hours.
- Fluticasone Propionate works as an antiinflammatory agent, reducing swelling and mucus buildup in the airways, thereby improving lung function and reducing asthma/COPD symptoms.

This combination is particularly beneficial for patients with moderate to severe asthma or COPD who require regular maintenance therapy.

Indications

Asthma

- Maintenance therapy for persistent asthma in adults and adolescents (above 12 years)
- Prevention of exercise-induced bronchospasm (EIB) in asthma patients

 Reduction of asthma exacerbations in patients not adequately controlled on inhaled corticosteroids alone

Chronic Obstructive Pulmonary Disease (COPD)

- Management of COPD symptoms, including chronic bronchitis and emphysema
- Prevention of COPD exacerbations in patients with a history of frequent flare-ups
- Improves lung function and reduces the need for rescue medications

Dosage & Administration

- As prescribed by a healthcare professional
- Typically, one capsule twice daily (morning and evening) via a dry powder inhaler (DPI) device
- Do not swallow the capsule; it must be used only in the prescribed inhalation device
- After each use, rinse the mouth with water to prevent oral fungal infections

Missed Dose:

- If a dose is missed, take it as soon as possible. If
 it is close to the next dose, skip the missed
 dose and continue with the regular schedule.
- Do not take a **double dose** to compensate for a missed dose.

Warnings & Precautions

General Precautions:

- Not for emergency use This medication does not relieve sudden asthma attacks. A shortacting bronchodilator (e.g., Salbutamol) should be used for quick relief.
- Regular monitoring is essential for patients with prolonged corticosteroid use to check for

side effects such as osteoporosis, adrenal suppression, or cataracts.

- Use with caution in:
 - Patients with cardiovascular diseases, as it may cause increased heart rate or palpitations.
 - Patients with diabetes, as corticosteroids may affect blood sugar levels.
 - Patients with osteoporosis, as corticosteroids can reduce bone mineral density.
 - Glaucoma and cataracts patients, as inhaled steroids can increase intraocular pressure.

Contraindications:

- Hypersensitivity to Salmeterol, Fluticasone Propionate, or any excipients in the formulation
- Acute bronchospasm or worsening asthma attacks
- Patients with severe milk protein allergy, as some dry powder inhalers contain lactose

Possible Side Effects

Most side effects are **mild and temporary**, but some may require medical attention.

Common Side Effects:

- Throat irritation, hoarseness, or cough
- Headache or dizziness
- Muscle cramps or joint pain
- Mild tremors or nervousness

Serious but Rare Side Effects:

- Oral Candidiasis (thrush): Fungal infection in the mouth; can be prevented by rinsing the mouth after each use.
- Increased heart rate (tachycardia) or palpitations
- Paradoxical bronchospasm (worsening breathing difficulty after inhalation) — If this occurs, stop use immediately and seek medical attention.

 Adrenal suppression – Long-term use may affect the adrenal glands, leading to hormonal imbalances.

Regular follow-ups with a healthcare provider are recommended to monitor side effects.

Storage Instructions

- Store at a temperature below 30°C in a dry place.
- Keep away from moisture and direct sunlight.
- Keep out of reach of children.
- Do not remove the capsule from the blister until ready to use.

Additional Information:

- For best results, **use the inhaler correctly** as instructed by a healthcare provider.
- If symptoms do not improve or worsen, consult a doctor immediately.
- This medication is intended for long-term management and should not be stopped suddenly without medical advice.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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