

Flutialfa S 500 Inhaler

Salmeterol (25 mcg) + Fluticasone Propionate (500 mcg) Inhaler

Category: Respiratory / Bronchodilator and Anti-inflammatory

Dosage Form: Inhaler (Metered Dose Inhaler)

Description:

The Salmeterol (25 mcg) + Fluticasone Propionate (500 mcg) Inhaler is a combination medication used in the management of asthma and chronic obstructive pulmonary disease (COPD). This inhaler contains Salmeterol, a long-acting bronchodilator, and Fluticasone Propionate, a potent corticosteroid. The combination works synergistically to improve lung function, relieve asthma symptoms, and prevent exacerbations by reducing inflammation in the airways and promoting long-lasting bronchodilation.

This inhaler is typically prescribed for patients who require combination therapy to control asthma or COPD symptoms. Salmeterol helps relax the muscles of the airways, making it easier to breathe, while Fluticasone Propionate reduces inflammation in the airways, helping to prevent asthma attacks and flare-ups of COPD.

Composition (Per Inhalation):

- Salmeterol (as xinafoate): 25 mcg
- Fluticasone Propionate: 500 mcg

- **Excipients: Propellant and other ingredients to aid in the inhalation process.**

Indications:

- 1. Asthma Management:**
 - For the long-term control of asthma in adults and children aged 12 years and older. It helps to prevent and control symptoms such as wheezing, shortness of breath, and coughing.
- 2. Chronic Obstructive Pulmonary Disease (COPD):**
 - For the maintenance treatment of COPD in adults, including individuals with chronic bronchitis or emphysema. It helps reduce symptoms such as wheezing, coughing, and difficulty breathing.
- 3. Preventing Exacerbations:**
 - It reduces the frequency of exacerbations and improves overall lung function, leading to better control of asthma or COPD.

Dosage and Administration:

- **Adults and Children (12 years and older):**
 - The usual dose is 1 inhalation (25 mcg of Salmeterol and 500 mcg of Fluticasone Propionate) twice daily, in the morning and

evening, or as prescribed by your healthcare provider.

- Do not exceed 2 inhalations per day (1 in the morning and 1 in the evening).
- The inhaler should be used regularly even when the patient is feeling well, to prevent asthma symptoms or COPD flare-ups.
- **Children (under 12 years):**
 - This inhaler is not recommended for children under 12 years of age. Alternative therapies may be considered.

Note: If a dose is missed, take it as soon as possible, unless it is time for the next dose. Do not double the dose to make up for a missed dose.

Mechanism of Action:

1. Salmeterol (Long-Acting Beta-2 Agonist):

- Salmeterol works by stimulating the beta-2 receptors in the smooth muscles of the airways, causing the muscles to relax and the airways to open up. This helps to improve airflow and make it easier to breathe. The effects of Salmeterol last for up to 12 hours, providing long-term relief from bronchoconstriction.

2. Fluticasone Propionate (Corticosteroid):

- Fluticasone Propionate is an anti-inflammatory medication that works by reducing

inflammation in the airways. It inhibits the release of inflammatory mediators, such as prostaglandins and leukotrienes, that contribute to airway swelling, narrowing, and increased mucus production. Regular use helps to prevent asthma attacks and flare-ups of COPD by controlling chronic airway inflammation.

Contraindications:

- **Hypersensitivity:**
 - Contraindicated in individuals who have a known allergy to Salmeterol, Fluticasone Propionate, or any of the excipients in the inhaler.
 - **Acute Asthma Exacerbations:**
 - Not for the treatment of acute asthma attacks or acute COPD flare-ups. A fast-acting bronchodilator (such as a short-acting beta agonist like albuterol) should be used during these situations.
 - **Primary treatment for COPD or asthma:**
 - This medication should not be used as a rescue inhaler during sudden breathing problems.
-

Warnings and Precautions:

1. Use with Caution in:

- **Cardiovascular Disease:** Salmeterol (a beta-2 agonist) may cause cardiovascular side effects such as increased heart

rate or blood pressure.

Caution is advised in individuals with heart disease or arrhythmias.

- **Infections:** Corticosteroids like Fluticasone Propionate may suppress the immune response, increasing susceptibility to infections. Be cautious if you have a history of frequent infections or are at higher risk for infections (e.g., tuberculosis or fungal infections).
- **Adrenal Insufficiency:** Long-term use of inhaled corticosteroids may lead to suppression of the adrenal glands. Symptoms of adrenal insufficiency may include weakness, fatigue, or nausea.

2. Monitor for Symptoms of Worsening Asthma:

- If you notice worsening symptoms, such as increased shortness of breath, chest tightness, or the need to use your rescue inhaler more frequently, consult a healthcare provider immediately.

3. Hyperglycemia:

- Inhaled corticosteroids, particularly at high doses, may lead to elevated blood sugar levels. Monitor blood glucose levels if you have diabetes or are at risk of developing diabetes.

4. Growth Suppression in Children:

- Long-term use of inhaled corticosteroids may affect growth in children. Regular monitoring of growth in pediatric patients using this medication is recommended.

Adverse Effects:

- **Common Side Effects:**

- Sore throat, hoarseness, or oral candidiasis (thrush) due to the corticosteroid. Rinsing the mouth after each use can help prevent these issues.
- Headache or dizziness.
- Coughing or throat irritation.
- Muscle or joint pain (more common with prolonged use).

- **Serious Side Effects:**

- Chest pain, palpitations, or increased heart rate (due to Salmeterol).
- Osteoporosis, especially with long-term use.
- Adrenal suppression or immune system suppression, increasing susceptibility to infections.
- Growth suppression in children with prolonged use.

Drug Interactions:

- **Beta-Blockers:**

- Beta-blockers may reduce the effectiveness of Salmeterol and should generally be avoided in patients using this medication unless prescribed for other conditions.

- **Corticosteroids (systemic or other inhaled forms):**

- Concurrent use of other systemic corticosteroids or inhaled corticosteroids can increase the risk of side effects such as adrenal suppression or osteopenia.

- **Diuretics (e.g., furosemide):**
 - Diuretics may increase the risk of low potassium levels when combined with Salmeterol. Monitoring of potassium levels is recommended.
- **Antifungal and Antiviral Medications:**
 - Some medications, such as ritonavir (a protease inhibitor), can increase the concentration of Fluticasone Propionate in the blood, leading to an increased risk of systemic side effects from corticosteroids.

- **Monitor Use:** Regularly assess the effectiveness and any side effects. If asthma or COPD symptoms worsen or do not improve, consult a healthcare provider.
- **Rinse Mouth After Use:** To reduce the risk of oral thrush, rinse the mouth after each use and clean the inhaler as directed.

Note: This inhaler should be used as part of a comprehensive asthma or COPD management plan, including avoiding triggers and following other prescribed treatments.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

TM: Trademark Applied for

Storage Instructions:

- Store the inhaler in a cool, dry place, away from heat and moisture.
- Keep the inhaler at room temperature (15–30°C).
- Do not store in the bathroom or areas with high humidity.
- Keep the inhaler out of the reach of children.
- Ensure the inhaler is tightly sealed after use.

Key Points for Use:

- **Salmeterol + Fluticasone Propionate Inhaler** is intended for long-term management of asthma and COPD, not for immediate relief during acute attacks.
- **Proper Technique:** It is important to use the inhaler properly to ensure that the medication reaches the lungs effectively. Instruct patients to follow inhaler instructions carefully.