Information For the User Formoterol (6mcg) + Fluticasone Propionate (50mcg) Inhaler

Flutialfa F 50 Inhaler

Brand Name: Flutialfa F 50 Inhaler

Dosage Form: Metered-Dose Inhaler (MDI)

Composition:

Each actuation contains:

Formoterol Fumarate IP 6 mcg (as dry powder) Fluticasone Propionate IP 50 mcg (as dry powder)

Therapeutic Segment:

Respiratory / Anti-Asthmatic Segment

Therapeutic Indication:

Indicated for the maintenance treatment of asthma and chronic obstructive pulmonary disease (COPD) in patients requiring both a long-acting bronchodilator and an inhaled corticosteroid. It helps control airway inflammation, reduce bronchial hyperreactivity, and relieve symptoms such as wheezing, shortness of breath, and coughing.

Mechanism of Action:

- Formoterol is a long-acting β_2 -adrenergic agonist (LABA) that relaxes bronchial smooth muscles, causing bronchodilation and improving airflow.
- **Fluticasone Propionate** is an inhaled corticosteroid that suppresses airway inflammation, reduces swelling and mucus production, and helps prevent asthma exacerbations.
- The combination provides both rapid symptom relief and long-term asthma control.

Dosage & Administration:

- Usually, 1–2 inhalations twice daily or as prescribed by the physician.
- Shake the inhaler well before use.
- Inhale deeply and hold breath for 5–10 seconds after actuation.
- Rinse mouth after each use to prevent oral thrush.

Contraindications:

- Hypersensitivity to formoterol, fluticasone, or any component of the formulation.
- Acute asthma attacks requiring immediate relief.

Warnings & Precautions:

- Not for relief of acute bronchospasm.
- Use with caution in patients with cardiovascular disorders, diabetes, or thyroid disorders.
- Monitor growth in pediatric patients during prolonged use.

• Discontinue and seek medical advice if paradoxical bronchospasm, severe allergic reactions, or worsening asthma occurs.

Side Effects:

- Common: Oral thrush, hoarseness, cough, headache, tremor, palpitations.
- Rare: Hypokalemia, arrhythmia, adrenal suppression (with prolonged use), hyperglycemia.

Storage:

Store below 30°C in a cool, dry place. Protect from heat, sunlight, and moisture. Keep out of reach of children.

Packaging:

Flutialfa F 50 Inhaler is available as a metered-dose inhaler containing 60–120 actuations per device.

Schedule:

Schedule H Drug – To be sold by retail on the prescription of a Registered Medical Practitioner only.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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

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