

Information For the User
Formoterol (6mcg) + Budesonide (400mcg)

Buditerm F 400 Inhaler

Formoterol (6 mcg) + Budesonide (400 mcg) Inhaler: Product Information

Brand Name: Formoterol (6 mcg) + Budesonide (400 mcg) Inhaler

Generic Name: Formoterol and Budesonide

Strength:

- **Formoterol:** 6 mcg per inhalation
 - **Budesonide:** 400 mcg per inhalation
- Dosage Form:** Metered-dose inhaler (MDI)

Indications:

Formoterol (6 mcg) + Budesonide (400 mcg) Inhaler is a combination medication used for the **maintenance treatment** of **asthma** and **chronic obstructive pulmonary disease (COPD)**. It provides long-term relief from symptoms such as wheezing, shortness of breath, and chest tightness.

1. **Asthma:**
 - Maintenance therapy in asthma patients who are not adequately controlled on a single medication.
 - Prevents **bronchoconstriction** and reduces airway inflammation, improving breathing.
2. **Chronic Obstructive Pulmonary Disease (COPD):**
 - Long-term management of COPD to help reduce the frequency of exacerbations and improve lung function.

Mechanism of Action:

- **Formoterol:** Formoterol is a **long-acting beta-2 adrenergic agonist (LABA)** that works by **relaxing the smooth muscles** in the airways, leading to **bronchodilation**. This helps to **open the airways** and facilitate better airflow, providing relief from breathing difficulties.
- **Budesonide:** Budesonide is a **corticosteroid** that reduces

inflammation in the airways. It works by inhibiting the release of **inflammatory mediators** (like prostaglandins and leukotrienes), which results in decreased swelling, mucus production, and airway restriction.

The combination of these two medications helps manage both **bronchoconstriction** and **inflammation**, providing improved asthma and COPD control.

Dosage and Administration:

- **Adults and Adolescents (12 years and older):**
 - **Recommended Dose: 1 inhalation (6 mcg Formoterol + 400 mcg Budesonide)** twice daily (morning and evening), or as directed by your doctor.
 - Use the inhaler **regularly** to achieve the best results. **Do not exceed the prescribed dose.**
- **Instructions for Use:**
 1. **Shake the inhaler well** before each use.
 2. **Remove the cap** from the mouthpiece.
 3. **Exhale fully** before placing the mouthpiece in your mouth.
 4. **Inhale deeply** and press down on the canister to release the medication.
 5. **Hold your breath** for about 10 seconds or as long as comfortable, then exhale slowly.
 6. If a second dose is required, wait for about **30 seconds** before repeating the steps.
 7. After use, **rinse your mouth** with water and spit it out to reduce the risk of oral thrush.

Contraindications:

- **Hypersensitivity** to formoterol, budesonide, or any component of the inhaler.
- **Severe hypersensitivity** reactions such as **anaphylaxis** or **angioedema**.

Warnings and Precautions:

- **Not for Immediate Relief:** This inhaler is for **maintenance therapy**. For immediate relief of acute asthma symptoms or COPD flare-ups, a **short-acting bronchodilator** should be used.
- **Paradoxical Bronchospasm:** Rarely, the inhalation of **formoterol** may cause **paradoxical bronchospasm** (worsening of asthma or COPD symptoms). If this occurs, **discontinue the inhaler** and seek medical attention immediately.
- **Corticosteroid Side Effects: Budesonide** can cause **systemic side effects** if used for prolonged periods, such as:
 - **Osteoporosis, cataracts, glaucoma.**
 - **Adrenal suppression and growth retardation** in children.
 - **Immunosuppression**, making the patient more vulnerable to infections.
- **Cardiovascular Effects: Formoterol** may cause side effects like **tachycardia** (increased heart rate) or **palpitations**. Caution should be exercised in individuals with **heart disease, hypertension, or arrhythmias**.

Side Effects:

Common Side Effects:

- **Headache.**
- **Throat irritation** or dry mouth.
- **Coughing** or hoarseness.

Serious Side Effects (less common):

- **Paradoxical bronchospasm.**
- **Oral thrush** or fungal infections in the mouth or throat.
- **Pneumonia**, particularly in COPD patients.
- **Hypersensitivity reactions** such as swelling, rash, or trouble breathing.
- **Cardiovascular issues** (palpitations, elevated heart rate).

Drug Interactions:

- **CYP3A4 Inhibitors:** Co-administration with **strong CYP3A4 inhibitors** (such as **ketoconazole** or **ritonavir**) may increase the plasma concentration of **budesonide**, leading to a higher risk of corticosteroid-related side effects.

- **Diuretics: Diuretics** may increase the risk of **hypokalemia**, and this risk may be potentiated by **formoterol**.
- **Other Inhaled Medications:** Caution should be exercised when using **other inhaled medications** to avoid excessive dosing or side effects.

Storage:

- Store the inhaler at **room temperature** (15°C to 30°C / 59°F to 86°F).
- Keep the inhaler away from **moisture** and **direct sunlight**.
- **Do not freeze.**
- Keep out of reach of children.

Patient Counseling Information:

- **Inhaler Technique:** Ensure you understand the correct technique for using the **inhaler** to ensure the medication reaches your lungs.
- **Rinse Mouth After Use:** To prevent **oral thrush** or fungal infections, rinse your mouth with water after using the inhaler.
- **Rescue Inhaler:** For acute asthma attacks or sudden breathing problems, always use a **rescue inhaler**.
- **Follow-Up Appointments:** Regular follow-up with your doctor is important to assess the effectiveness of the therapy and to monitor for potential side effects.

This information provides a comprehensive overview of the **Formoterol 6 mcg + Budesonide 400 mcg Inhaler**. Always follow your healthcare provider's instructions and report any side effects or concerns you may have.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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