

Buditerm F 200 Inhaler

Formoterol (6mcg) + Budesonide (200mcg) Inhaler: Product Information

Brand Name: Formoterol 6 mcg + Budesonide 200 mcg Inhaler

Generic Name: Formoterol and Budesonide

Strength:

- **Formoterol:** 6 mcg per actuation
- **Budesonide:** 200 mcg per actuation
- Dosage Form:** Metered-dose inhaler (MDI)

Indications:

Formoterol and Budesonide Inhaler is indicated for the **long-term management** of **asthma** and **chronic obstructive pulmonary disease (COPD)** in adults and children over the age of 12 years. It is used for:

1. **Asthma:**
 - **Maintenance therapy** to reduce inflammation and bronchoconstriction.
 - Used in combination with other asthma treatments when **long-acting bronchodilation** and **anti-inflammatory** effects are required to control symptoms.
2. **COPD:**
 - **Long-term maintenance treatment** for patients with COPD, to improve lung function and reduce the risk of exacerbations.

This combination helps reduce **airway inflammation**, improve **bronchial dilation**, and control both **asthmatic** and **COPD symptoms** over time.

Mechanism of Action:

- **Formoterol:**
Formoterol is a **long-acting beta-agonist (LABA)** that works by stimulating **beta-2 adrenergic receptors** in the smooth muscle of the airways, leading to **bronchodilation**. This opens the airways, improving airflow and

helping relieve symptoms such as **wheezing**, **shortness of breath**, and **tightness in the chest**.

- **Budesonide:**
Budesonide is a **corticosteroid** that works by **reducing inflammation** in the lungs. It inhibits the release of pro-inflammatory mediators such as **leukotrienes** and **prostaglandins**, helping to prevent airway **swelling** and **narrowing**. Budesonide also reduces the risk of acute asthma exacerbations and COPD flare-ups.

The combination of both drugs provides **dual action** in controlling both the underlying inflammation and the bronchoconstriction, improving overall respiratory function.

Dosage and Administration:

- **Adults and Adolescents (12 years and older):**
 - The maximum dose is **2 inhalations per day** (one in the morning and one in the evening). If higher doses are required, a healthcare provider may recommend an alternative regimen.
 - Use the inhaler as directed. **Do not exceed** the prescribed dose.
- **How to Use the Inhaler:**
 - Shake the inhaler well before use.
 - Exhale completely and place the mouthpiece of the inhaler in your mouth.
 - Press down on the inhaler to release the medication while inhaling deeply and slowly.
 - Hold your breath for about **10 seconds** or as long as comfortable.
 - If a second inhalation is required, wait **30 seconds** and repeat the process.
 - After use, rinse your mouth with water to reduce the risk of **oral thrush** and other infections caused by the corticosteroid.

Warnings and Precautions:

- **Not for Acute Symptoms:** This medication is for **maintenance therapy** only and is not

intended for the relief of acute asthma or COPD attacks. Always have a **rescue inhaler** available for sudden breathing difficulties.

- **Infections:** Corticosteroids may suppress the immune system, increasing the risk of infections, including **oral thrush**, **pneumonia**, and **tuberculosis**. Patients should be advised to **rinse their mouth** after each use to reduce the risk of oral fungal infections.

Side Effects:

Common Side Effects:

- Throat irritation or hoarseness.
- Cough or dry mouth.
- Headache.
- Muscle cramps or tremors.
- Nausea or vomiting.

Serious but Rare Side Effects:

- **Paradoxical bronchospasm** (worsening of asthma or breathing difficulties).
- **Oral thrush** or **fungal infections** in the mouth or throat.
- **Pneumonia** (especially in COPD patients).
- **Hypersensitivity reactions**, including **rash**, **swelling**, or **difficulty breathing**.
- **Cardiovascular effects:** Increased heart rate, palpitations, or **QT prolongation**.

Drug Interactions:

- **CYP3A4 Inhibitors:** Co-administration with **strong CYP3A4 inhibitors** (e.g., **ketoconazole**, **itraconazole**) may increase **budesonide** levels, raising the risk of **systemic corticosteroid side effects**.
- **Beta-Blockers:** **Beta-blockers** (e.g., **propranolol**) can reduce the effectiveness of **formoterol** and should be avoided or used with caution in patients receiving this combination inhaler.
- **Other Inhaled Medications:** Care should be taken when using other inhaled medications, particularly **short-acting beta-agonists** (SABAs), to avoid excessive dosing or side effects.

- **Diuretics:** **Diuretics** (e.g., **furosemide**) may increase the risk of **hypokalemia**, which can be exacerbated by **formoterol**.

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 store in **freezing** temperatures.
- **Keep out of reach of children.**
- Check the inhaler for the number of remaining doses, and dispose of the inhaler when it is empty.

Patient Counseling Information:

- **Mouth Care:** Rinse your mouth with water after each use to reduce the risk of **oral thrush** and other oral infections.
- **Use Regularly:** Take this medication regularly even if you feel better. This helps control symptoms and prevent flare-ups.
- **Emergency Plan:** Always keep a **rescue inhaler** (short-acting bronchodilator) with you in case of sudden worsening of asthma or COPD symptoms.

This information provides a detailed overview of the **Formoterol (6 mcg) + Budesonide (200 mcg) Inhaler**. Follow the prescribed regimen carefully, and consult your healthcare provider if you experience any concerns or side effects.

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