

Buditerm F Respule

Product Information: Formoterol (20mcg) + Budesonide (0.5mg) Respule

Composition:

- **Formoterol Fumarate (20 mcg):** A long-acting beta-2 adrenergic receptor agonist (LABA) that relaxes airway muscles, improving airflow and breathing.
 - **Budesonide (0.5 mg):** An inhaled corticosteroid (ICS) that reduces airway inflammation and prevents asthma symptoms.
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Pharmacological Class:

- **Combination of Long-Acting Beta-Agonist (LABA) and Inhaled Corticosteroid (ICS).**
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Indications:

This combination is indicated for:

- **Asthma:** For maintenance treatment and prevention of symptoms in adults and children aged 6 years and above.
 - **Chronic Obstructive Pulmonary Disease (COPD):** For the management of airflow obstruction and reduction of exacerbations in adults.
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Mechanism of Action:

1. **Formoterol:** Stimulates beta-2 adrenergic receptors in bronchial smooth muscles, leading to relaxation of airways, reduced bronchospasm, and improved airflow.
 2. **Budesonide:** Acts by inhibiting inflammatory responses in the airway, reducing swelling, and preventing hyperresponsiveness to allergens and irritants.
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Dosage and Administration:

- **Adults and children over 6 years:**
 - 1 respule (20mcg/0.5mg) nebulized twice daily.
 - Use as per physician's recommendation based on severity.
 - **How to use:**
 - Shake the respule well before use.
 - Twist open and squeeze the contents into the nebulizer chamber.
 - Use a nebulizer to inhale the medication as instructed by a healthcare professional.
 - Ensure the nebulizer is cleaned thoroughly after use.
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Contraindications:

- **Hypersensitivity to Formoterol, Budesonide, or any excipients.**

- **Acute severe asthma or COPD exacerbations (this is not a rescue medication).**
 - **Coughing during inhalation, nausea, mild throat irritation.**
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Warnings and Precautions:

- **Not for acute symptoms: Use a short-acting bronchodilator (e.g., salbutamol) for immediate relief.**
 - **Long-term use of LABA without corticosteroids can increase the risk of asthma-related deaths. Use only in combination therapy.**
 - **Use with caution in:**
 - **Patients with cardiovascular disorders (e.g., arrhythmias, hypertension).**
 - **Diabetics: Formoterol may increase blood glucose.**
 - **Patients with infections or suppressed immunity due to Budesonide.**
 - **Patients with a history of osteoporosis or glaucoma.**
 - **Monitor for oral candidiasis (thrush); rinse the mouth after each use.**
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Adverse Effects:

- **Formoterol:**
 - **Tremors, palpitations, headache, muscle cramps.**
 - **Rare: Paradoxical bronchospasm.**
 - **Budesonide:**
 - **Hoarseness, sore throat, oral thrush.**
 - **Long-term use: Risk of adrenal suppression or osteoporosis.**
 - **Combined:**
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Drug Interactions:

- **Beta-blockers: May reduce the effect of Formoterol.**
 - **Diuretics: Increased risk of hypokalemia with Formoterol.**
 - **Ketoconazole and CYP3A4 inhibitors: May increase Budesonide levels.**
 - **Avoid using with other long-acting beta-agonists or corticosteroids unless prescribed.**
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Use in Special Populations:

- **Pregnancy: Use only if the potential benefits justify the risks.**
 - **Lactation: Use with caution; limited data on excretion in breast milk.**
 - **Pediatrics: Recommended in children aged 6 years and above, under medical supervision.**
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Storage:

- **Store below 25°C. Protect from light and moisture.**
 - **Do not freeze.**
 - **Once opened, use immediately or discard unused portions.**
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Packaging:

**Available in unit-dose respules containing
20 mcg Formoterol and 0.5 mg Budesonide
per 2 mL.**

Patient Instructions:

- 1. Adherence: Use the medication regularly for long-term control, even if symptoms improve.**
 - 2. Nebulizer use: Ensure proper technique for effective delivery.**
 - 3. Oral care: Rinse your mouth with water after inhalation to prevent oral thrush.**
 - 4. Emergency care: Always carry a rescue inhaler for acute symptoms.**
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This combination of Formoterol and Budesonide provides effective control of airway inflammation and bronchoconstriction, improving overall respiratory function and quality of life in asthma and COPD patients. Always consult a healthcare provider for tailored advice.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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

Panchkula-134113

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