

Buditem L Respule

Product Information: Levosalbutamol (1.25mg) + Budesonide (0.5mg) Respule

Composition:

- **Levosalbutamol (1.25mg):** A selective beta-2 adrenergic agonist that works as a bronchodilator.
 - **Budesonide (0.5mg):** An inhaled corticosteroid that reduces inflammation in the airways.
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Pharmacological Class:

- **Levosalbutamol: Selective Beta-2 Adrenergic Agonist (Bronchodilator).**
 - **Budesonide: Inhaled Corticosteroid (ICS).**
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Indications:

This combination of Levosalbutamol and Budesonide is indicated for:

- **Asthma:** To provide both bronchodilation and anti-inflammatory effects for long-term management of asthma symptoms in patients aged 6 years and older.
- **Chronic Obstructive Pulmonary Disease (COPD):** To reduce inflammation and improve airflow in patients with COPD.
- **Acute exacerbations:** In combination therapy to provide relief from wheezing, shortness of breath, and other respiratory distress.

Mechanism of Action:

1. **Levosalbutamol:** A selective beta-2 adrenergic receptor agonist, it stimulates the beta-2 receptors in the bronchial smooth muscles, leading to muscle relaxation, bronchodilation, and improved airflow. It helps reduce symptoms of bronchospasm.
 2. **Budesonide:** Inhaled corticosteroid that works by reducing airway inflammation, inhibiting inflammatory cell migration, and suppressing cytokine release. It helps to prevent asthma attacks and reduces the frequency of COPD exacerbations by decreasing airway hyper-responsiveness.
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Dosage and Administration:

- **Adults and children 6 years and older:**
 - 1 respule (1.25mg Levosalbutamol and 0.5mg Budesonide) nebulized twice daily, or as directed by a physician.
- **How to use:**
 - Shake the respule well before use.
 - Open the respule by twisting the top off.
 - Squeeze the contents into the nebulizer chamber.
 - Use a nebulizer machine to inhale the solution.
 - Follow the instructions provided for proper nebulizer usage and cleaning.
 - Use as per the doctor's prescribed regimen.

Contraindications:

- **Hypersensitivity to Levosalbutamol, Budesonide, or any other component of the formulation.**
- **Acute asthma attacks: This product is not for immediate relief of acute asthma or COPD exacerbations (use a short-acting beta-agonist instead).**
- **Untreated fungal, bacterial, or viral infections: Use with caution in patients with active infections.**

Warnings and Precautions:

- **Not for acute relief: Levosalbutamol is for long-term control of asthma and COPD symptoms. Use a short-acting bronchodilator for rapid relief of acute symptoms.**
- **Systemic corticosteroid effects: Long-term use of Budesonide can cause adrenal suppression, growth retardation in children, and osteoporosis. Regular monitoring is recommended.**
- **Paradoxical bronchospasm: Rarely, inhaled bronchodilators can cause sudden worsening of wheezing and shortness of breath. If this occurs, stop the medication immediately and consult a healthcare provider.**
- **Cardiovascular disease: Levosalbutamol should be used with caution in patients with cardiovascular conditions, such as heart disease or hypertension, as it can increase heart rate and blood pressure.**
- **Infection risk: Corticosteroids like Budesonide may reduce immune function, increasing the risk of infections. Rinse mouth after use to avoid oral thrush.**

Adverse Effects:

- **Levosalbutamol:**
 - Tremors, headache, dizziness, palpitations, muscle cramps.
 - Rare: Paradoxical bronchospasm, allergic reactions.
- **Budesonide:**
 - Hoarseness, throat irritation, oral candidiasis (thrush), coughing.
 - Rare: Increased risk of infection, adrenal suppression, or bone mineral density loss with long-term use.
- **Combined effects:**
 - Dry mouth, irritation in the throat, or cough after nebulization.

Drug Interactions:

- **Beta-blockers: May reduce the effectiveness of Levosalbutamol, especially non-selective beta-blockers.**
- **CYP3A4 inhibitors (e.g., ketoconazole, ritonavir): May increase Budesonide levels, requiring dose adjustment.**
- **Diuretics: Use with caution as they may increase the risk of low potassium levels, especially when combined with Levosalbutamol.**
- **Other corticosteroids: Increased risk of systemic corticosteroid effects when used with other oral or inhaled corticosteroids.**

Use in Special Populations:

- **Pregnancy: Use only if the potential benefit justifies the risk. Levosalbutamol and Budesonide should be used during pregnancy only when absolutely necessary and prescribed by a doctor.**
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- **Lactation:** Both drugs are excreted in breast milk in small amounts. Consult a doctor before use while breastfeeding.
 - **Pediatrics:** Not recommended for children under 6 years of age. Use with caution in children, particularly with regards to the potential impact of Budesonide on growth.
 - **Geriatrics:** No specific dose adjustment is needed, but caution is advised due to possible comorbidities such as cardiovascular disease or osteoporosis.
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Storage:

- Store below 25°C in a cool, dry place.
 - Protect from light and moisture.
 - Do not freeze.
 - Once opened, use immediately or discard any unused solution.
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Packaging:

- **Respules:** Available in 2mL unit doses, typically sold in a pack of 10 or 20 respules.
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Key Points for Patients:

1. **Inhalation technique:** Ensure proper nebulizer technique to receive the full dose.
2. **Rinse your mouth after use** to prevent oral thrush or irritation.
3. **Not for acute asthma attacks:** Always have a fast-acting inhaler for emergencies.
4. **Monitor for side effects:** Inform your healthcare provider of any unusual symptoms, such as palpitations, tremors, or signs of infection.

5. **Adherence:** Use the medication regularly as prescribed to maintain control over asthma or COPD.
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Levosalbutamol (1.25mg) and Budesonide (0.5mg) Respule is a combination therapy designed to control asthma and COPD symptoms, combining the bronchodilatory effects of Levosalbutamol with the anti-inflammatory benefits of Budesonide. Always use under the guidance of a healthcare provider to optimize treatment outcomes.

Manufactured in India for:

CafoliTM
L I F E C A R E

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(An ISO 9001: 2015 Certified Co.)

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