

Critsal 1.25 Respule

Product Information: Levosalbutamol (1.25mg) + Ipratropium (500mcg) Respule

Composition:

- **Levosalbutamol (1.25mg):** A selective beta-2 adrenergic agonist (bronchodilator).
 - **Ipratropium Bromide (500mcg):** A short-acting muscarinic antagonist (anticholinergic bronchodilator).
-

Pharmacological Class:

- **Levosalbutamol:** Beta-2 adrenergic agonist (Bronchodilator).
 - **Ipratropium Bromide:** Anticholinergic agent (Muscarinic antagonist).
-

Indications:

This combination therapy of Levosalbutamol and Ipratropium is indicated for:

- **Chronic Obstructive Pulmonary Disease (COPD):** For the maintenance treatment of chronic bronchitis and emphysema.
- **Asthma:** In cases of severe asthma exacerbations requiring additional bronchodilation.
- **Acute Bronchospasm:** For the relief of acute bronchospasm in COPD and asthma.

This combination is beneficial for patients who require both beta-2 adrenergic and anticholinergic bronchodilation to relieve airflow obstruction.

Mechanism of Action:

1. Levosalbutamol:

- A selective beta-2 adrenergic agonist that stimulates beta-2 receptors in the smooth muscle of the airways, leading to bronchodilation and easing the passage of air into the lungs.
- It relaxes bronchial smooth muscle, reducing bronchospasm and improving airflow, which is helpful in treating conditions like asthma and COPD.

2. Ipratropium Bromide:

- An anticholinergic agent that works by blocking muscarinic receptors in the bronchial smooth muscle. This prevents acetylcholine from binding to these receptors, thus reducing bronchoconstriction and promoting bronchodilation.
 - Ipratropium helps in reducing mucus production and prevents further narrowing of the airways.
-

Dosage and Administration:

- **Adults and Children over 12 years:**

- 1 respule (1.25mg Levosalbutamol + 500mcg Ipratropium) nebulized 2-4 times daily or as prescribed by a healthcare provider.
- Acute exacerbations: May be used up to 4 times per day as directed by a doctor.
- **How to use:**
 - Shake the respule well before opening.
 - Open the respule by twisting off the top.
 - Squeeze the contents into a nebulizer chamber.
 - Use a nebulizer machine to inhale the solution.
 - Follow the nebulizer manufacturer's instructions for proper use and maintenance.
 - Discard any unused solution after a single use.

- **Not for acute relief:** This combination should not be used as a rescue medication during an acute asthma attack or COPD exacerbation. Use a short-acting beta-agonist for immediate relief.
- **Glaucoma risk:** Use with caution in patients with a history of glaucoma, especially narrow-angle glaucoma, as Ipratropium may increase intraocular pressure.
- **Urinary retention:** May cause difficulty urinating, particularly in patients with prostatic hypertrophy or bladder neck obstruction.
- **Cardiovascular disease:** Levosalbutamol should be used cautiously in patients with heart disease, as it may cause palpitations, tachycardia, or elevated blood pressure.
- **Paradoxical bronchospasm:** Rarely, inhaled bronchodilators can cause paradoxical bronchospasm. If this occurs, discontinue use immediately and seek medical attention.
- **Renal and Hepatic impairment:** Use with caution in patients with severe renal or hepatic impairment. Regular monitoring may be necessary.

Contraindications:

- **Hypersensitivity to Levosalbutamol, Ipratropium Bromide, or any component of the formulation.**
- **History of hypersensitivity to atropine or its derivatives.**
- **Acute bronchospasm:** This medication is not intended for the rapid relief of acute bronchospasm (use a short-acting beta-agonist instead).
- **Narrow-angle glaucoma or urinary retention due to the anticholinergic properties of Ipratropium.**

Adverse Effects:

- **Levosalbutamol:**
 - **Common:** Tremors, headache, palpitations, tachycardia, muscle cramps.
 - **Less common:** Nervousness, dizziness, dry mouth.
 - **Rare:** Paradoxical bronchospasm, allergic

Warnings and Precautions:

reactions (e.g., rash, angioedema).

- **Ipratropium Bromide:**
 - **Common:** Dry mouth, throat irritation, cough.
 - **Less common:** Nausea, headache, dizziness, blurred vision.
 - **Rare:** Urinary retention, acute glaucoma, allergic reactions (e.g., rash, urticaria).
 - **Combined effects:**
 - **Mild** throat irritation, hoarseness, or a bad taste after nebulization.
 - **Very rare:** Anaphylaxis or hypersensitivity reactions.
-

Drug Interactions:

- **Beta-blockers:** May reduce the effectiveness of Levosalbutamol. Beta-blockers, especially non-selective ones, can antagonize the bronchodilator effect of Levosalbutamol.
 - **Anticholinergics:** Caution is advised if other anticholinergic drugs are used concurrently, as this can increase the risk of anticholinergic side effects (e.g., dry mouth, constipation).
 - **Diuretics:** Use with caution as they may increase the risk of low potassium levels, especially when combined with Levosalbutamol.
 - **CYP3A4 inhibitors:** May increase the plasma concentration of Ipratropium.
-

Use in Special Populations:

- **Pregnancy:** Use only when the potential benefit justifies the risk. Levosalbutamol and Ipratropium should be used during pregnancy only when prescribed by a healthcare provider.
 - **Lactation:** Both drugs are excreted in breast milk in small amounts. Use with caution and consult a healthcare provider before use while breastfeeding.
 - **Pediatrics:** Safe for children over 12 years. Safety and efficacy in children under 12 have not been established.
 - **Geriatrics:** Use with caution in older adults, particularly those with comorbidities such as glaucoma or cardiovascular disease.
-

Storage:

- Store below 25°C in a cool, dry place.
 - Protect from light and moisture.
 - Do not freeze.
 - Keep out of reach of children.
-

Packaging:

- Available in 2mL unit-dose respules, typically in packs of 10 or 20 respules.
-

Patient Instructions:

1. Shake the respule well before use.
2. Open the respule by twisting off the top.
3. Squeeze the contents into the nebulizer chamber and inhale the

medication via the nebulizer machine.

- 4. Follow the nebulizer instructions provided by your healthcare provider.**
 - 5. Rinse your mouth after nebulization to avoid throat irritation or dryness.**
 - 6. Do not use more than the recommended dose unless directed by your doctor.**
 - 7. Keep track of how often you are using the medication and consult your doctor for long-term management.**
-

Levosalbutamol (1.25mg) + Ipratropium (500mcg) Respule is a combination therapy designed to treat chronic bronchospasm and improve lung function in patients with asthma and COPD. By combining the bronchodilatory effects of Levosalbutamol and Ipratropium, this medication helps provide both short-term and long-term relief, supporting improved breathing and reduced inflammation. Always use as directed by your healthcare provider to manage symptoms effectively.

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