

Buditerm 0.5 Respule

Budesonide (0.5mg) Respule

Category:

Corticosteroid (Anti-inflammatory)

Dosage Form:

Respiratory Solution (Inhalation Solution)
for Nebulization

Strength:

Budesonide 0.5 mg per 2 mL respule

Description:

Budesonide is a potent corticosteroid used to manage asthma and chronic obstructive pulmonary disease (COPD) by reducing inflammation in the airways. Budesonide (0.5mg) Respule is a ready-to-use inhalation solution designed for use in a nebulizer. It delivers the active ingredient directly to the lungs, helping to reduce inflammation, swelling, and mucus production. The formulation is intended for patients who are unable to use inhalers or need additional support for their respiratory condition.

Composition (per 2 mL respule):

- Budesonide: 0.5 mg

- Inactive ingredients: Sodium chloride, citric acid, and purified water (as solvents).
-

Indications:

1. Asthma:

- To treat and prevent asthma attacks by reducing inflammation and bronchoconstriction.
- Long-term control of asthma symptoms in patients who are unable to use metered-dose inhalers or need additional support.

2. Chronic Obstructive Pulmonary Disease (COPD):

- To manage inflammation and reduce flare-ups in patients with COPD, improving lung function and quality of life.

3. Other Respiratory Conditions:

- Can be used off-label in the treatment of other chronic respiratory conditions where airway inflammation is a concern.
-

Mechanism of Action:

Budesonide is a corticosteroid that works by inhibiting the release of substances in the body that cause inflammation. It reduces swelling and irritation in the airways, making breathing easier. By acting locally in the lungs, it helps to reduce bronchospasm and mucus production,

preventing asthma attacks and reducing symptoms of COPD.

Dosage and Administration:

- **Adults and Children over 12 years:**
 - Typically, 1 respule (0.5 mg/2 mL) once or twice daily, as directed by the physician.
 - The usual dose is based on the severity of the condition and the individual response.
- **Children (6 months to 12 years):**
 - The dose is usually 1 respule (0.5 mg/2 mL) once or twice daily. For children, the dose may be adjusted depending on response and the severity of symptoms.
- **Infants (less than 6 months):**
 - Consult a pediatrician for appropriate dosing.

Note: The solution should be used in a nebulizer as prescribed. Shake the respule before use, and ensure it is administered through an appropriate nebulizer device. The medication should be inhaled until the solution is finished, usually in 5–10 minutes.

Contraindications:

- **Hypersensitivity:** Known allergy to budesonide or any of the excipients in the formulation.
- **Acute Asthma Attacks:** Not intended for the immediate relief of acute asthma attacks or acute bronchospasm. In case of an acute attack, a fast-acting inhaler should be used.

Precautions:

1. Inhaled Corticosteroid Use:

- Long-term use of inhaled corticosteroids may lead to systemic effects, including adrenal suppression. Regular monitoring may be required, particularly for high doses over extended periods.

2. Infections:

- May increase the risk of infections such as pneumonia and tuberculosis. Patients should be monitored for signs of respiratory infections.

3. Children and Growth Monitoring:

- In children, long-term use should be monitored for any signs of growth suppression. Regular check-ups are necessary.

4. Liver Disease:

- Caution is advised in patients with severe liver impairment, as the metabolism of budesonide may be affected.

5. Not for Acute Attacks:

- Budesonide is not a rescue medication for sudden asthma or COPD attacks. Always keep a fast-acting bronchodilator on hand.

Adverse Effects:

Common Side Effects:

- Hoarseness or voice changes
- Cough or throat irritation
- Oral thrush (fungal infection in the mouth)

- Dry mouth or throat
- Nasal congestion

Serious Side Effects (Rare):

- Adrenal insufficiency (especially with long-term use)
- Decreased bone density (osteoporosis)
- Cataracts or glaucoma
- Growth retardation in children with prolonged use
- Serious allergic reactions (rash, swelling, difficulty breathing)

Drug Interactions:

1. **Ritonavir (Antiviral):**
 - Ritonavir can increase the levels of budesonide in the blood, increasing the risk of side effects.
2. **Other Steroids:**
 - Caution should be exercised when used with other corticosteroids, as the risk of systemic corticosteroid side effects may be increased.
3. **CYP3A4 Inhibitors:**
 - Drugs that inhibit CYP3A4 (e.g., ketoconazole) may increase the plasma levels of budesonide.

Storage Instructions:

- Store at room temperature (between 15°C and 30°C).
- Protect from light and moisture.
- Keep out of reach of children.
- Do not use after the expiration date indicated on the package.

- Refrigeration is not required, but the respules should be stored in a cool, dry place.

Key Benefits:

- **Effective Long-Term Control:** Helps manage asthma and COPD symptoms, reducing inflammation and improving lung function over time.
- **Localized Action:** Delivers the medication directly to the lungs, minimizing systemic side effects.
- **Convenient Formulation:** The respule provides a convenient, ready-to-use solution for patients who may have difficulty using inhalers.

Note: Always follow the prescribed dosage and consult your healthcare provider for personalized treatment. Regular follow-up appointments are essential for monitoring the effects of budesonide, especially with prolonged use.

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