

Tioprime Rota Cap

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Composition:

Each hard gelatin rota capsule contains:

- **Tiotropium Bromide Monohydrate IP** equivalent to **Tiotropium 18 mcg**
- **Excipients** – q.s.

Dosage Form:

Rota Capsule (For inhalation use only with a Rotahaler)

Therapeutic Category:

Long-Acting Muscarinic Antagonist (LAMA) – Bronchodilator

Pharmacology & Mechanism of Action:

Tiotropium is a long-acting anticholinergic bronchodilator. It binds to M3 muscarinic receptors in the airway smooth muscle, inhibiting acetylcholine-mediated bronchoconstriction. This leads to prolonged bronchodilation, making it effective for once-daily maintenance treatment in obstructive airway diseases.

Tiotropium exhibits high affinity for muscarinic receptors and dissociates slowly, ensuring sustained 24-hour bronchodilation.

Indications:

- Maintenance treatment of bronchospasm associated with Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema
- Reduces COPD exacerbations and improves lung function
- May be used as add-on therapy in moderate to severe asthma uncontrolled on ICS + LABA

Dosage and Administration:

- One capsule once daily via Rotahaler
- Inhalation should be at the same time each day
- Do not swallow the capsule; puncture using Rotahaler and inhale contents
- Rinse mouth after inhalation to prevent throat irritation or dry mouth

Contraindications:

- Known hypersensitivity to tiotropium or atropine derivatives
- Patients with a history of hypersensitivity to lactose or milk proteins (contains lactose)

Warnings and Precautions:

- Not for relief of acute bronchospasm
- Use with caution in patients with narrow-angle glaucoma, prostatic hyperplasia, or bladder neck obstruction
- Ensure proper inhalation technique for optimal therapeutic benefit
- Discontinue if signs of paradoxical bronchospasm or allergic reaction occur

Drug Interactions:

- Concomitant use with other anticholinergic drugs may increase the risk of side effects
- No significant drug interactions observed in clinical use

Adverse Effects:

- Common: Dry mouth, throat irritation, cough
- Less common: Constipation, dizziness, blurred vision, urinary retention
- Rare: Hypersensitivity reactions, including rash, pruritus, and anaphylaxis

Overdose:

Overdose may lead to anticholinergic symptoms such as dry mouth, blurred vision, or palpitations. Supportive and symptomatic treatment is recommended.

Storage:

Store in a cool, dry place below 25°C
 Protect from moisture and light
 Keep capsules in blister until use
 Keep out of reach of children

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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