

Information For the User  
Formoterol (6mcg) + Glycopyrrolate (25mcg) Rota Capsule

# Glycopryl FG Rota Cap

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## Composition:

Each hard gelatin rota capsule contains:

- **Formoterol Fumarate IP** equivalent to **Formoterol 6 mcg**
- **Glycopyrronium Bromide IP** equivalent to **Glycopyrrolate 25 mcg**
- **Excipients** – q.s.

## Dosage Form:

Rota Capsule (for inhalation use only with a compatible rotahaler device)

## Therapeutic Category:

Long-Acting Beta-2 Agonist (LABA) + Long-Acting Muscarinic Antagonist (LAMA) – Dual Bronchodilator

## Pharmacology & Mechanism of Action:

Formoterol is a selective long-acting beta-2 adrenergic agonist (LABA) that acts on bronchial smooth muscle to produce bronchodilation. It provides rapid onset and sustained bronchodilation by stimulating intracellular adenyl cyclase, increasing cAMP levels.

Glycopyrrolate is a long-acting muscarinic antagonist (LAMA) that inhibits acetylcholine-mediated bronchoconstriction by blocking M3 receptors on airway smooth muscle. It improves airflow, reduces air trapping, and lowers the frequency of COPD exacerbations.

The combination offers synergistic bronchodilation by targeting both  $\beta_2$  and muscarinic pathways, providing better control of symptoms and lung function in COPD.

## Indications:

- Maintenance treatment of airflow obstruction in patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD)
- Reduces the frequency of COPD exacerbations
- Improves pulmonary function and quality of life in COPD patients

## Dosage and Administration:

- One capsule to be inhaled once daily using a rotahaler
- Do not swallow the capsule
- Administer at the same time each day for consistent control
- Rinse mouth after inhalation to reduce the risk of oral side effects

## Contraindications:

- Hypersensitivity to Formoterol, Glycopyrrolate, or any component of the formulation
- Patients with severe hypersensitivity to lactose (contains lactose)
- Not indicated for the treatment of acute asthma or bronchospasm

### **Warnings and Precautions:**

- Not a rescue medication – should not be used for acute episodes of bronchospasm
- Caution in patients with cardiovascular disorders, seizures, thyrotoxicosis, or diabetes mellitus
- May cause paradoxical bronchospasm; discontinue immediately if it occurs
- Monitor for symptoms of urinary retention or glaucoma in susceptible patients

### **Drug Interactions:**

- Use with other adrenergic drugs may enhance sympathomimetic effects
- Beta-blockers may reduce effectiveness of Formoterol
- Caution when used with MAO inhibitors or tricyclic antidepressants
- Avoid co-administration with other anticholinergic agents

### **Adverse Effects:**

- Common: Dry mouth, throat irritation, headache, tremor
- Less common: Palpitations, dizziness, urinary retention, cough
- Rare: Hypersensitivity reactions including rash, urticaria, and bronchospasm

### **Overdose:**

Symptoms of overdose may include tremor, tachycardia, palpitations, and hypertension. Supportive symptomatic treatment should be initiated. No specific antidote exists.

### **Storage:**

Store below 25°C in a dry place  
Protect from direct sunlight and moisture  
Keep capsules in the original blister pack until use  
Keep out of reach of children

Manufactured in India for:



**Cafoli Lifecare Pvt. Ltd.**

**(An ISO 9001: 2015 Certified Co.)**

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