

Indacaterol 110 µg & Glycopyrronium 50 µg

COMPOSITION

Each capsule contains Indacaterol Maleate INN equivalent to Indacaterol 110 µg & Glycopyrronium Bromide BP equivalent to Glycopyrronium 50 µg.

PHARMACOLOGY

Indica-G is a combination of two bronchodilators. Indacaterol, a long acting β_2 -adrenergic agonist (LABA) and Glycopyrronium, a long acting muscarinic receptor antagonist (LAMA). When Indacaterol & Glycopyrronium are administered together, they provide additive efficacy due to their different mode of action targeting different receptors and pathways to achieve bronchial smooth muscle relaxation.

INDICATION

Airflow obstruction in patients with Chronic obstructive pulmonary disease (COPD), Chronic bronchitis and Emphysema. Not indicated to treat acute deteriorations of Chronic obstructive pulmonary disease and asthma. The safety and effectiveness of Indacaterol in asthma have not been established.

DOSAGE AND ADMINISTRATION

Route of Administration : Oral inhalation.

Indica-G Rotacap must not be swallowed as the intended effects on the lungs will not be obtained. The contents of Indica-G Rotacap are only for oral inhalation and should only be used with the ^{ACME'S} Easyhaler.

Indica-G Rotacap should be administered once daily every day at the same time of the day by the orally inhaled route only. If a dose is missed, the next dose should be taken as soon as it is remembered. Do not use Indica-G Rotacap more than one time in every 24 hours.

Indica-G Rotacap must always be stored in the blister, and only removed IMMEDIATELY BEFORE USE. No dose adjustment is required for geriatric patients, patients with mild and moderate hepatic impairment, or renally impaired patients.

No data are available for subjects with severe hepatic impairment.

Indica-G Rotacap is not indicated for use in the pediatric population. Safety and efficacy have not been established.

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Indica-G is not indicated for the treatment of asthma. It is contraindicated in patients with a history of hypersensitivity to Indacaterol or Glycopyrronium or to any of the ingredients of the product.

WARNINGS AND PRECAUTIONS

Rarely, serious (sometimes fatal) breathing problems have happened to people with asthma using a long-acting inhaled beta agonist (Salmeterol). Since Indica-G is similar to Salmeterol, it might cause these serious breathing problems. Indica-G has not been shown to be safe or effective to treat asthma and is not approved for this use.

SIDE EFFECTS

Common : The most commonly reported adverse effects were cough, nasopharyngitis, headache, nausea, oropharyngeal pain.

Rare : Hypersensitivity reactions, paradoxical bronchospasm, tachycardia, pruritis and dizziness.

USE IN PREGNANCY & LACTATION

There are no data from the use of Indica-G Rotacap in pregnant women.

Indica-G should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known that the active component of Indica-G is excreted in human milk. Since ingredients of Indica-G has been detected in the milk of lactating rats, caution should be exercised when Indica-G is administered to nursing women.

DRUG INTERACTIONS

With Medicine : No specific drug-drug interaction studies were conducted with Indica-G. Information on Indica-G is based on the potential for interactions for each of its two components.

Indacaterol shows interaction with Adrenergic Drugs, Xanthine Derivatives, Steroids, or Diuretics. Concomitant treatment with xanthine derivatives, steroids, or diuretics may potentiate any hypokalemic effect of Indacaterol. Beta-adrenergic receptor antagonists (beta-blockers) and Indacaterol may interfere with the effect of each other when administered concurrently.

There is a potential for an interaction with concomitantly used anticholinergic medications that leads to an additive pharmacological effect. Therefore, avoid co-administration of Indica-G with other anticholinergic-containing drugs as this may lead to an undesirable anticholinergic effects.

With food & others : Drug-Food interactions have not been established. No clinically relevant effect of food would be expected and therefore, a food interaction study was not conducted.

OVERDOSAGE

The expected signs and symptoms associated with over dosage of Indacaterol are angina, hypertension or hypotension, tachycardia, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, muscle cramps, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, metabolic acidosis and insomnia. Signs and symptoms of overdosage with Glycopyrronium are increased intraocular pressure causing pain, vision disturbances or reddening of the eye. Cardiac monitoring (including electrocardiography) is recommended in cases of overdose.

PHARMACEUTICAL PRECAUTIONS

- Rotacap is to be used through ^{ACME'S} Easyhaler.
- Rotacap is not to be swallowed.
- Do not exceed the recommended dose.
- Insert the Rotacap in the ^{ACME'S} Easyhaler just prior to use, as Rotacap exposed to moisture may not be pierced easily.

STORAGE

Keep all medicines out of reach of children.

Store below 30° C and dry place, protected from light.

PACKING

Each box contains 3x10 capsules (Rotacap) in Alu-Alu blister strips.

***Further information is available on request**



Manufactured by:

The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness