

Catium™ ConviCap

Indacaterol 27.5 µg & Glycopyrronium 15.6 µg

Presentation

Catium™ ConviCap: Each capsule contains Indacaterol Maleate INN equivalent to 27.5 µg of Indacaterol and Glycopyrronium Bromide BP equivalent to 15.6 µg of Glycopyrronium.

Description

Indacaterol Maleate is a selective b2-adrenergic agonist. Its chemical name is (R)-5-[2-(5,6-Diethylindan-2-ylamino)-1-hydroxyethyl]-8 hydroxy-1H-quinolin-2-one maleate. Indacaterol Maleate has a molecular weight of 508.56 and its empirical formula is C₂₄H₂₈N₂O₃·C₄H₄O₄. Indacaterol Maleate is a white to very slightly grayish or very slightly yellowish powder. Indacaterol Maleate is freely soluble in N-methylpyrrolidone and dimethylformamide, slightly soluble in methanol, ethanol, propylene glycol and polyethylene glycol 400, very slightly soluble in water, isopropyl alcohol and practically insoluble in 0.9% sodium chloride in water, ethyl acetate and n-octanol. Glycopyrronium is a long-acting, specific antimuscarinic agent, in clinical medicine often called an anticholinergic. It has a similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, inhibition of M3-receptors at the smooth muscle results in relaxation. The high potency and slow receptor dissociation found its clinical correlate in significant and long-acting bronchodilation in patients with COPD.

Indication and Uses

Indacaterol & Glycopyrronium combination is indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Dosage and Administrations

The recommended dosage of Indacaterol & Glycopyrronium combination DPI is inhalation of the contents of one capsule twice daily with the ConviHaler device.

Side-effects

Inhaled medicines may cause inhalation-induced bronchospasm, dehydration, dry mouth, constipation, dizziness, insomnia, skin and subcutaneous tissue disorders & immune system disorders.

Precautions

Indacaterol and Glycopyrronium combination is as a twice daily maintenance bronchodilator should not be used for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur after administration of Indacaterol and Glycopyrronium combination inhalation powder. As with other anticholinergic drugs, Glycopyrronium should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction.

Use in Pregnancy & Lactation

Pregnancy:

There is a limited amount of data from the use of Indacaterol and Glycopyrronium combination in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at clinically relevant doses.

Lactation:

Indacaterol and Glycopyrronium combination should not be used in pregnant or nursing women unless the expected benefit outweighs any possible risk to the unborn child or the infant.

Contraindications

Contraindicated for the treatment of patients who have demonstrated hypersensitivity to any of its active ingredients like Indacaterol or Glycopyrronium.

Drug interactions

Adrenergic drugs, xanthine derivatives, steroids, or diuretics, non-potassium sparing diuretics, monoamine oxidase inhibitors, tricyclic antidepressants, QTc prolonging drugs, beta-blockers, inhibitors of cytochrome P₄₅₀ 3A₄ and P-gp efflux transporter may interact with Indacaterol.

Overdose

An overdose of indacaterol is likely to lead to exaggerated effects typical of beta2-adrenergic stimulants, i.e. tachycardia, tremor, palpitations, headache, nausea, vomiting, drowsiness, ventricular arrhythmias, metabolic acidosis, hypokalaemia and hyperglycaemia. High doses of Glycopyrronium may lead to anticholinergic signs and symptoms.

Storage

- 1) Store at temperature not exceeding 25°C but do not freeze.
- 2) Store in cool and dry place, protected from light.

Commercial Pack

Catium™ ConviCap: Each box contains 5 blister strips of 6 capsules.