

Caterol™ ConviCap

Indacaterol Maleate

Presentation

Caterol™ 75 ConviCap: Each capsule contains Indacaterol Maleate INN equivalent to 75 µg Indacaterol.

Caterol™ 150 ConviCap: Each capsule contains Indacaterol Maleate INN equivalent to 150 µg Indacaterol.

Description

Indacaterol Maleate is a selective β₂-adrenergic agonist. Its chemical name is (R)-5-[2-(5,6-Diethylindan-2-ylamino)-1-hydroxyethyl]-8hydroxy-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.

Indication & Uses

Indacaterol Maleate is indicated for maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema.

Dosage and Administration

The recommended dose is 75-150 µg according to patient's condition once a day, The maximum dose is 300 microgram once daily with regard to breathlessness, particularly for patients with severe COPD.

Side Effects

The common side effects experienced are Cough, Oropharyngeal pain, Nasopharyngitis, Headache, Nausea. Few side effects may result like musculoskeletal and connective tissue disorders: muscle spasm, musculoskeletal pain, peripheral edema diabetes mellitus, hyperglycemia, sinusitis, upper respiratory tract infection.

Use in Pregnancy and Lactation

Pregnancy:

Pregnancy Category C.

There are no adequate and well-controlled studies with Indacaterol in pregnant women. Indacaterol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation:

Caution should be used when Indacaterol is administered to nursing women.

Contraindications

All LABA are contraindicated in patients with asthma without use of a long-term asthma control medication. Indacaterol is not indicated for the treatment of asthma. Indacaterol is contraindicated in patients with a history of hypersensitivity to indacaterol or to any of the ingredients.

Precautions

Indacaterol should not be initiated in patients with acutely deteriorating COPD.

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

In COPD patients, single doses of 10 times, the maximum recommended therapeutic dose were associated with a moderate increase in pulse rate, systolic blood pressure and QTc interval. An overdose of Indacaterol is likely to lead to exaggerated effects typical of β₂-adrenergic stimulants, i.e. tachycardia, tremor, palpitations, headache, nausea, vomiting, drowsiness, ventricular arrhythmias, metabolic acidosis, hypokalaemia and hyperglycaemia.

Storage


- Protect from light, store in cool & dry place
- Do not store above 30 °C.
- Keep out of the reach of children
- Protect from freezing
- Insert the ConviCap in the ConviHaler just prior to use to protect from deterioration by moisture

Commercial Pack

Caterol™ 75 ConviCap: Each box contains 5 alu-alu blister strips of 6 capsules.

Caterol™ 150 ConviCap: Each box contains 5 alu-alu blister strips of 6 capsules.

Manufactured by

 **Incepta Pharmaceuticals Ltd**

Savar, Dhaka, Bangladesh