

NEW DRUG UPDATE

Drug Name:	indacaterol
Trade Name (Manufacturer):	Arcapta™ (Novartis)
Form:	Capsules containing powder for inhalation
Strength:	75 mcg
FDA Approval:	July 1, 2011
Market Availability:	Launch anticipated in January 2012
FDA Approval Classification:	Standard review
Classification:	Specific Therapeutic Class (HIC3): Beta-Adrenergic Agents (J5D)

Indication:¹ Indacaterol (Arcapta), a long-acting beta₂-agonist bronchodilator, is indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). Indacaterol is not indicated for the treatment of asthma.

Contraindications/Warnings: Indacaterol is contraindicated in patients with asthma without use of a long-acting asthma controller medication. Indacaterol contains a similar black box warning shared by other long-acting inhaled beta₂-agonists regarding an increased risk of asthma-related death.

Indacaterol should not be initiated in acutely deteriorating COPD patients, nor should it be used for the relief of acute symptoms. The recommended dose of indacaterol should not be exceeded. Life-threatening paradoxical bronchospasm can occur with indacaterol. Caution should be used in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or sensitivity to sympathomimetic drugs when using indacaterol.

Drug Interactions: Concurrent use of other adrenergic drugs can potentiate the effect of indacaterol. Xanthine derivatives, steroids, diuretics, or non-potassium-sparing diuretics may potentiate hypokalemia or ECG changes. Extreme caution should be used when giving indacaterol to patients taking MAO inhibitors, tricyclic antidepressants, or drugs that prolong the QTc interval. Beta-blockers may decrease the effectiveness of indacaterol.

Common Adverse Effects: In trials performed by the manufacturer, the following events occurred most frequently: cough (6.5 percent versus 4.5 percent with placebo), oropharyngeal pain (2.2 versus 0.7 percent), nasopharyngitis (5.3 versus 2.7 percent), headache (5.1 versus 2.5 percent), and nausea (2.4 vs. 0.9 percent).

Special Populations:

Pediatrics: The safety and effectiveness of roflumilast in pediatrics has not been established.

Pregnancy: Pregnancy Category C

Geriatrics: In clinical trials, no overall differences in effectiveness or safety were reported for this population.

Renal Impairment: No dosage adjustment is necessary in patients with renal impairment.

Hepatic Impairment: No dosage adjustment is necessary in patients with hepatic impairment. Studies were not performed in patients with severe impairment.

Dosages: Indacaterol capsules are for inhalation use only. The recommended dose is one 75 mcg capsule inhaled once daily at the same time each day with the Neohaler device. Capsules should remain stored in the blister packaging until immediately before use.

Clinical Trials: A literature search was performed using “indacaterol”. Placebo-controlled trials were included in the absence of comparative trials.

Available published studies with indacaterol include comparative trials with other products indicated for the treatment of COPD, but exceed the FDA-approved dosing of 75 mcg daily.

Six manufacturer trials enrolled 5,474 patients with a clinical diagnosis of COPD who were 40 years or older, had a smoking history of at least 10 pack years, had a post-bronchodilator FEV1 between 30 and 80 percent of the predicted normal value and a post-bronchodilator ratio of FEV1 over FVC of less than 70 percent.² Assessment of efficacy in these COPD trials was based on FEV1. The primary efficacy endpoint was 24-hour post-dose trough FEV1 after 12 weeks of treatment in all trials. Other efficacy variables included other FEV1 and FVC time points, rescue medication use, symptoms, and health-related quality of life.

In all six trials, all doses of indacaterol tested (75 mcg, 150 mcg, 300 mcg, and 600 mcg) showed significantly greater 24-hour post-dose trough FEV1 compared to placebo at 12 weeks. Results of the trials which compared indacaterol at the dose of 75 mcg once daily to placebo were statistically significant in favor of indacaterol, with trough FEV1 of 1.38-1.49 L compared to 1.26-1.35 L for placebo. Post-dose response times compared to placebo were generally in favor of indacaterol. In COPD trials including the 75 mcg dose, patients treated with indacaterol used less daily rescue albuterol during the trial compared to patients treated with placebo.

Other Drugs Used for Condition: Drugs indicated for use in the treatment of COPD include anticholinergic-containing products such as ipratropium (Atrovent[®]) inhalers and nebulizer solutions, ipratropium/albuterol (Duoneb[®]) nebulizer solution, and tiotropium (Spiriva[®]). Fluticasone/salmeterol (Advair[®]) and budesonide/formoterol (Symbicort[®]), glucocorticoid combinations with long-acting beta agonists, are also indicated for this disease. Roflumilast (Daliresp[™]) is a non-bronchodilating oral option for the treatment of COPD.

Place in Therapy: Indacaterol joins several other long-acting beta₂-agonist bronchodilator products for the treatment of COPD. This product has data available comparing it to established COPD treatments, both anticholinergics and beta-agonists, but those data use a higher daily dose compared to the FDA-approved recommendation of 75 mcg daily. Unless indacaterol becomes available in combination with an inhaled steroid, utilization of this product line is expected to be low in the Medicaid patient population.

References

¹ Arcapta [package insert]. East Hanover, NJ; Novartis; August 2010.

² Arcapta [package insert]. East Hanover, NJ; Novartis; August 2010.