

26-4-2010

Pharmacotherapeutic report

Indacaterol (Onbrez®) for the indication 'COPD'

Medicine. Indacaterol 150 µg inhalation powder in hard capsules

Registered indication. "Maintenance treatment of respiratory obstruction in adults with chronic obstructive lung disease (COPD)".

Dose. 150 µg 1X daily, with Onbrez Breezhaler inhalator. Maximum dose: 300 µg 1X daily.

Working mechanism. When inhaled, indacaterol works as a bronchodilator. Indacaterol is a partial agonist of  $\beta_2$ -adrenergic receptors. Such agonists stimulate the enzyme intracellular adenylylase, which catalyses the conversion of ATP into cyclic AMP. Increased levels of cyclic AMP cause bronchial smooth muscles to relax.

### **Summary of therapeutic value**

**Favourable effects.** Based on the studies available, after 3 months administration to patients with moderately-severe or severe chronic obstructive pulmonary disease, the effect of indacaterol on FEV<sub>1</sub> and symptoms is similar to that of formoterol and salmeterol. There are insufficient reports on the results of indacaterol at the recommended dose after a relevant follow-up of  $\geq 6$  months.

**Unfavourable effects.** The side effects of indacaterol are the same as those of the treatments with which it was compared.

**Experience.** Experience with indacaterol is more limited than with the treatments with which it was compared.

**Applicability.** The range of application of indacaterol is just as broad as that of that of the treatments with which it was compared.

**Ease of use.** Indacaterol is just as easy to use as the treatments with which it was compared.

**Final conclusion.** The therapeutic value of indacaterol in the treatment of chronic obstructive pulmonary disease is equal to that of formoterol and salmeterol.

*The original text of the summary of this pharmacotherapeutic report was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of the summary of the CFH-report.*

*Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.*