

Pharmacotherapeutic report, summary

Acclidinium (Eklira® Genuair®) for the indication 'COPD'

Approved on 26 November 2012 by the Medicinal Products Reimbursement Committee (CFH)

Medicine. 322 µg acclidinium (as bromide).

Registered indication. "Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)"

Posology. 322 µm 2x/day, with the Genuair inhaler device. Every delivered dose (the dose leaving the mouthpiece) contains 375 µg acclidinium bromide, the equivalent of 322 µg acclidinium. This corresponds to a metered dose of 400 µg acclidinium bromide equivalent to 343 µg acclidinium.

Mechanism of action. Acclidinium is a competitive, selective muscarinic receptor antagonist (also known as an anticholinergic) with a greater affinity for M3 muscarinic receptors than for M2 receptors. The bronchodilation is mainly due to a local effect on the bronchial smooth muscles. The effect occurs within 30 minutes, is at its maximum with 1-3 hours and continues for 12 hours.

Summary of the therapeutic value

Intended effects. Two available placebo-controlled studies show that acclidinium has a larger clinical effect on the pre-dose FEV1 and quality of life than a placebo treatment in patients with moderate to severe COPD. Acclidinium leads to a larger reduction in moderate to severe exacerbations than placebo. Based on the only - unpublished - indirect comparison, the effect on FEV1 and symptoms seems comparable with tiotropium after six weeks treatment.

Unintended effects. The side-effects of acclidinium are similar to those of tiotropium.

Experience. Experience with acclidinium is more limited compared to tiotropium.

Applicability. There are no major differences in applicability between acclidinium and tiotropium.

Ease of use. There are no major differences between acclidinium and tiotropium.

Final conclusion. For the treatment of COPD, the therapeutic value of acclidinium is equal to that of tiotropium.

*The original text of this excerpt from a **CFH-Report** of CVZ 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 CVZ's 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.