European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 April 2008
Doc.Ref. EMEA/CHMP/216404/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
AZOPT

International Nonproprietary Name (INN): ***brinzolamide***

On 24 April 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend a variation to the terms of the marketing authorisation for the medicinal product Azopt. The Marketing Authorisation Holder for this medicinal product is Alcon Laboratories (UK) Ltd.

The CHMP adopted a change to the indications to include use of Azopt as 'adjunctive therapy' with prostaglandin analogues.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Azopt will be as follows[***]:
"*Azopt is indicated to decrease elevated intraocular pressure in:*
- Ocular hypertension
- Open-angle glaucoma
as monotherapy in patients unresponsive to beta-blockers or in patients in whom beta-blockers are contra-indicated, or as adjunctive therapy to beta-blockers ***or to prostaglandin analogues****".*

[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

[***] The text in bold represents the new or the amended indication.

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