European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 September 2009
Doc.Ref.EMEA/CHMP/541231/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ONBREZ BREEZHALER

International Nonproprietary Name (INN): ***indacaterol maleate***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Onbrez Breezhaler, 150 µg, 300 µg, inhalation powder intended for maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Novartis Europharm Ltd.

The active substance of Onbrez Breezhaler is indacaterol maleate, a long-acting, beta2-adrenergic agonist medicinal product (ATC Code not yet assigned). When inhaled, indacaterol acts locally in the lung as a bronchodilator. The benefits with Onbrez Breezhaler are its ability to provide clinically significant improvements in lung function as measured by the forced expiratory volume in one second, over 24 hours when administered once a day. The most common side effects are: nasopharyngitis, cough, upper respiratory tract infection and headache. A pharmacovigilance plan for Onbrez Breezhaler, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: maintenance of bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD). The recommended dose of Onbrez Breezhaler is the inhalation of the content of one 150 microgram capsule once a day, using the Onbrez Breezhaler inhaler. The dose should only be increased on medical advice (up to the maximum dose 300 µg.
Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.
The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Onbrez Breezhaler and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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.

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