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

London, 26 June 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION[*]
for
VIMPAT

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

On 26 June 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,[**] recommending to grant a marketing authorisation for the medicinal product Vimpat, 50 mg, 100 mg, 150 mg, 200 mg, film-coated tablet, 15 mg/ml syrup, 10 mg/ml solution for infusion intended for adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older The applicant for this medicinal product is UCB Pharma S.A..

The active substance of Vimpat is lacosamide, an anti-epileptic medicinal product (ATC code: (N03AX18). A dual mode of action is hypothesised for Vimpat: it selectively enhances slow inactivation of voltage-gated sodium channels (VGSC), resulting in stabilization of hyperexcitable physiological neuronal excitability. In addition, it interacts with collapsin response mediator protein-2 (CRMP-2), a protein mainly expressed in the central nervous system (CNS) and involved in neuronal differentiation and axonal outgrowth.

The benefits with Vimpat are its antiepileptic effect as adjunctive treatment of partial seizures, which has been satisfactorily documented. Thirty-four percent of patients treated with Vimpat 200 mg/day and 40% of patients treated with Vimpat 400 mg/day showed response to treatment *vs* 23% in the placebo group. Response is defined as 50% reduction in seizure frequency from baseline to maintenance phase. The most common side effects are dizziness, headache, diplopia and nausea.

A pharmacovigilance plan for Vimpat, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Vimpat is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with epilepsy aged 16 years and older.

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 Vimpat 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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu