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

London, 19 February 2009
Doc.Ref. EMEA/CHMP/98344/2009

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

International Nonproprietary Name (INN): ***eslicarbazepine acetate***

On 19 February 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Exalief, 400 mg, 600 mg, 800 mg, tablets intended for adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation. The applicant for this medicinal product is BIAL - Portela & Ca,S.A.

The active substance of Exalief is Eslicarbazepine acetate, an Antiepileptic medicinal product (N03AF04) which is a prodrug of eslicarbazepine , third generation drug belonging to the family of carbamazepine and oxcarbazepine.

The benefits with Exalief are that, added to concomitant antiepileptic drugs it decreases the standardised frequency of seizures per month (median) from 7.7 to 5.0 on ESL 800 mg and from 8.0 to 4.6 on ESL 1200mg, versus a decrease from 7.0 to 6.4 seizures observed in the placebo group.

The percentage of responders (patients with a relative change in standardised seizure frequency ≥50% in comparison to baseline period) is also improved by ESL: 36.3% on ESL 800mg and 43.5% on ESL 1200mg, versus only 21.5% observed in the placebo group.

The most common side effects are dizziness, somnolence, headache, abnormal coordination, disturbed vision, nausea, rash, fatigue.

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

The approved indication is: adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation

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 Exalief and therefore recommends the granting of the marketing authorisation.

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* 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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