24 May 2012
EMA/CHMP/242764/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fycompa

perampanel

On 24 May 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fycompa, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg, film-coated tablet intended for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older. The applicant for this medicinal product is Eisai Europe Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Fycompa is perampanel, a non-competitive antagonist of the ionotropic α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) glutamate receptor on post-synaptic neurons (N03AX22). The precise mechanism by which perampanel exerts its antiepileptic effects in humans remains to be fully elucidated.

The benefits with Fycompa are its ability to reduce the frequency of seizures at doses of 4 mg/day, 8 mg/day and 12 mg/day as shown in three placebo controlled studies conducted in epilepsy subjects aged 12 years and older diagnosed with partial-onset seizures with or without secondarily generalised seizures. The most common side effects are dizziness and somnolence.

A pharmacovigilance plan for Fycompa will be implemented as part of the marketing authorisation.

The approved indication is: "Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Fycompa and therefore recommends the granting of the marketing authorisation.