19 November 2015
EMA/CHMP/742520/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Briviact

brivaracetam

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Briviact, intended for the treatment of partial-onset seizures. The applicant for this medicinal product is UCB Pharma SA.

Briviact will be available as 10 mg, 25 mg, 50 mg, 75 mg and 100 mg film-coated tablets, a 10 mg/ml oral solution, and a 10 mg/ml solution for injection/infusion. The active substance of Briviact is brivaracetam, an antiepileptic (ATC code: N03AX23) whose anticonvulsant activity is believed to be mediated mainly through interference with a protein called synaptic vesicle protein 2A.

The benefits with Briviact are its ability to reduce the frequency of partial-onset seizures in epilepsy patients when added to an existing regimen of antiepileptic medicines. The most common side effects are somnolence, dizziness and fatigue.

The full indication is:

"Briviact is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy."

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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