15 December 2016
EMA/CHMP/643488/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pregabalin Zentiva k.s.

pregabalin

On 15 December 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pregabalin Zentiva k.s., intended for the treatment of epilepsy, neuropathic pain and generalised anxiety disorder. The applicant for this medicinal product is Zentiva k.s.

Pregabalin Zentiva k.s. will be available as hard capsules (25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg). The active substance of Pregabalin Zentiva k.s. is pregabalin, a gamma-aminobutyric acid (GABA) analogue (ATC code N03AX16). Pregabalin modulates neuronal excitability in the central nervous system.

Pregabalin Zentiva k.s. is a generic of Lyrica, which has been authorised in the EU since 6 July 2004. Studies have demonstrated the satisfactory quality of Pregabalin Zentiva k.s., and its bioequivalence to the reference product Lyrica.

The full indication is:

"Neuropathic pain

Pregabalin Zentiva k.s. is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

Pregabalin Zentiva k.s. is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised anxiety disorder

Pregabalin Zentiva k.s. is indicated for the treatment of generalised anxiety disorder (GAD) in adults."

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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