28 January 2016
EMA/CHMP/15884/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zonisamide Mylan

zonisamide

On 28 January 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 Zonisamide Mylan, intended for the treatment of partial seizures, with or without secondary generalisation. The applicant for this medicinal product is Mylan S.A.S.

Zonisamide Mylan will be available as 25 mg, 50 mg and 100 mg hard capsules.

The active substance of Zonisamide Mylan is zonisamide, an antiepileptic (ATC code: N03AX15). Zonisamide acts by blocking voltage-sensitive sodium and calcium channels in the brain, thereby preventing the abnormal neuronal activity that leads to seizures in epilepsy patients. Furthermore, zonisamide has been shown to modulate the activity of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) and may therefore help stabilise neuronal activity.

Zonisamide Mylan is a generic of Zonegran, which has been authorised in the European Union since 10 March 2005. Studies have demonstrated the satisfactory quality of Zonisamide Mylan, and its bioequivalence to the reference product Zonegran. A question and answer document on generic medicines can be found here.

The full indication is:

"Zonisamide Mylan is indicated as:

- monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy (see section 5.1);
- adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation, in adults, adolescents, and children aged 6 years and above."

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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