

25 July 2013
EMA/CHMP/416989/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Zonegran zonisamide

On 25 July 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Zonegran. The marketing authorisation holder for this medicinal product is Eisai Ltd. They may request an examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication on *adjunctive therapy in the treatment of partial seizures with or without secondary generalisation* **to include adolescents and children aged 6 years and above.**

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

For information, the full indications for Zonegran will be as follows²:

Zonegran is indicated as:

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

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended indication.