



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2016
EMA/CHMP/581734/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Vimpat lacosamide

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Vimpat. The marketing authorisation holder for this medicinal product is UCB Pharma S.A.

The CHMP adopted an extension to the existing indication as follows²:

"Vimpat is indicated as **monotherapy and** adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent (16-18 years) patients with epilepsy".

Detailed recommendations 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 a decision on this change to 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

² **New text in bold**

