13 October 2016
EMA/CHMP/643479/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zebinix

eslicarbazepine acetate

On 13 October 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Zebinix. The marketing authorisation holder for this medicinal product is Bial - Portela & Cª, S.A.

The CHMP adopted an extension to the existing indication as follows[2]:

"Zebinix is indicated as adjunctive therapy in adults**, adolescents and children aged above 6 years,** with partial-onset seizures with or without secondary generalisation".

In addition, Zebinix will be available as an oral suspension (50 mg/ml).

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

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