17 September 2020
EMA/CHMP/471522/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Fycompa

perampanel

On 17 September 2020, 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 Fycompa. The marketing authorisation holder for this medicinal product is Eisai GmbH.

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

Fycompa (perampanel) is indicated for the adjunctive treatment of

- **partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older.**

- **primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE).**

~~Fycompa is indicated for the adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in adult and adolescent patients from 12 years of age with epilepsy.~~

~~Fycompa is indicated for the adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy (see section 5.1).~~

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**, removed text as ~~strikethrough~~

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