21 May 2015
EMA/CHMP/324747/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Kuvan

sapropterin

On 21 May 2015, 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 Kuvan. The marketing authorisation holder for this medicinal product is Merck Serono Europe Limited.

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

"Kuvan is indicated for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of **all ages**~~4 years of age and over~~ with phenylketonuria (PKU) who have been shown to be responsive to such treatment (see section 4.2)."

For information, the full indication for Kuvan will be as follows:

"Kuvan is indicated for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with phenylketonuria (PKU) who have been shown to be responsive to such treatment (see section 4.2).

Kuvan is also indicated for the treatment of hyperphenylalaninaemia (HPA) in adults and paediatric patients of all ages with tetrahydrobiopterin (BH4) deficiency who have been shown to be responsive to such treatment (see section 4.2)."

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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