16 December 2021
EMA/CHMP/732482/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sapropterin Dipharma

sapropterin

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sapropterin Dipharma, intended for the treatment of hyperphenylalaninemia (HPA).

The applicant for this medicinal product is Dipharma B.V.

Sapropterin Dipharma will be available as powder for oral solution (100 and 500 mg) and soluble tablets (100 mg). The active substance of Sapropterin Dipharma is sapropterin, a 'various alimentary tract and metabolism' medicinal product (ATC code: A16AX07). Sapropterin is a synthetic version of the naturally occurring tetrahydrobiopterin (6R-BH4), a cofactor of hydroxylases for phenylalanine, tyrosine and tryptophan.

Sapropterin Dipharma is a generic of Kuvan, which has been authorised in the EU since 2 December 2008. Studies have demonstrated the satisfactory quality of Sapropterin Dipharma, and its bioequivalence to the reference product Kuvan. A question and answer document on generic medicines can be found here.

The full indication is:

> Sapropterin Dipharma 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).
>
> Sapropterin Dipharma 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).
>
> Sapropterin Dipharma must be initiated and supervised by a physician experienced in the treatment of PKU and BH4 deficiency.

[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

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