26 July 2018
EMA/CHMP/395605/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kigabeq

vigabatrin

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a paediatric use marketing authorisation (PUMA) for the medicinal product Kigabeq, intended for the treatment of infantile spasms (West's syndrome) and resistant partial epilepsy (focal onset seizures) in infants and children. The applicant for this medicinal product is ORPHELIA Pharma SAS.

Kigabeq will be available as breakable soluble tablets (100 mg and 500 mg). The active substance of Kigabeq is vigabatrin, an antiepileptic (ATC code: N03AG04) whose anticonvulsant activity is mediated through the selective and irreversible inhibition of the enzyme responsible for the breakdown of GABA.

The benefits with Kigabeq are its ability to reduce the frequency of seizures in patients with infantile spasms when administered as monotherapy and in patients with resistant partial epilepsy when added to an existing regimen of antiepileptic medicines. The most common side effects are visual field defects, psychiatric disorders such as agitation, excitation, aggression, nervousness, depression and paranoid reaction, and nervous system disorders such as marked sedation, stupor and confusion.

Kigabeq is a hybrid medicine[2] of Sabril (500 mg, granules for oral solution), which has been authorised in the EU since 22 March 1993. Kigabeq contains the same active substance as Sabril, but is available in a lower strength of 100 mg (allowing a 50 mg dosing increment) in addition to the 500 mg strength. It can be administered through gastric tubes in patients who cannot swallow in addition to the regular oral administration route.

Studies have demonstrated the satisfactory quality of Kigabeq, and its bioequivalence to the reference product Sabril 500 mg.

The full indication is:

"Kigabeq is indicated in infants and children from 1 month to less than 7 years of age for:

- Treatment in monotherapy of infantile spasms (West's syndrome).

[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] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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- Treatment in combination with other antiepileptic medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated."

It is proposed that Kigabeq be prescribed by physicians specialized in epileptology, neurology or paediatric neurology.

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.