15 October 2020
EMA/CHMP/510338/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fintepla

fenfluramine

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fintepla[2], intended for the treatment of seizures associated with Dravet syndrome.

The applicant for this medicinal product is Zogenix ROI Limited.

Fintepla will be available as an oral solution (2.2 mg/ml). The active substance of Fintepla is fenfluramine, an antiepileptic. The precise mechanism of action is not known. Fenfluramine acts to release 5-HT (serotonin) and so increase stimulation of some brain 5-HT receptors, as well as acts on the sigma-1 receptor.

The benefits of Fintepla lie in its ability to help manage the seizures associated with Dravet syndrome. The most common side effects are decreased appetite, diarrhoea, pyrexia, fatigue, upper respiratory tract infection, lethargy, somnolence and bronchitis. Because of known risk of valvular heart disease and pulmonary arterial hypertension, though associated with higher doses of fenfluramine than those used for Dravet syndrome, echocardiography monitoring program is mandatory.

The full indication is:

> Fintepla is indicated for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older.

Fintepla should be initiated and supervised by physicians experienced in the treatment of epilepsy. It should be prescribed and dispensed according to a controlled access programme.

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.

[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] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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