23 July 2020
EMA/CHMP/377211/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fampridine Accord

fampridine

On 23 July 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 Fampridine Accord, intended to improve walking of adult patients suffering from multiple sclerosis with walking disability. The applicant for this medicinal product is Accord Healthcare S.L.U.

Fampridine Accord will be available as 10 mg prolonged-release tablets. The active substance of Fampridine Accord is fampridine, a potassium channel blocker (ATC code: N07XX07). By blocking potassium channels, fampridine reduces the leakage of ionic current through these channels, thereby prolonging repolarization and thus enhancing action potential formation in demyelinated axons and neurological function. By enhancing action potential formation, it may cause more impulses to be conducted in the central nervous system.

Fampridine Accord is a generic of Fampyra, which has been authorised in the EU since 20 July 2011. Studies have demonstrated the satisfactory quality of Fampridine Accord and its bioequivalence to the reference product Fampyra. A question and answer document on generic medicines can be found here.

The full indication is:

> Fampridine Accord is indicated for the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7).

It is proposed that Fampridine Accord be prescribed by physicians experienced in the treatment of multiple sclerosis.

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

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