24 March 2022
EMA/CHMP/122713/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Amifampridine SERB

amifampridine

On 24 March 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Amifampridine SERB, intended for the treatment of Lambert-Eaton myasthenic syndrome in adults.

The applicant for this medicinal product is SERB SA.

Amifampridine SERB will be available as 10 mg tablets. The active substance of Amifampridine SERB is amifampridine (ATC code: N07XX05). Amifampridine blocks voltage-dependent potassium channels, thereby prolonging pre-synaptic cell membrane depolarisation, which enhances the transport of calcium into the nerve ending. The resulting increase in intra-cellular calcium concentrations facilitates exocytosis of acetylcholine-containing vesicles, which in turn enhances neuromuscular transmission.

Amifampridine SERB is a generic of Firdapse, which has been authorised in the EU since 23 December 2019. Studies have demonstrated the satisfactory quality of Amifampridine SERB. The applicant claimed Amifampridine SERB has the same qualitative and quantitative composition in active substance and excipients, and the same pharmaceutical form as the reference medicinal product, and that the medicine is manufactured following the same process and at the same manufacturing sites. Therefore, the proposed product is considered bioequivalent to the reference product according to the Guideline of Investigation of Bioequivalence, as they are pharmaceutically equivalent and their bioavailability is univocally the same. A question and answer document on generic medicines can be found here.

The full indication is:

> Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

Amifampridine SERB should be prescribed by physicians experienced in the treatment of the disease.

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.