16 September 2021
EMA/CHMP/500803/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vumerity

diroximel fumarate

On 16 September 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 Vumerity, intended for the treatment of adult patients with relapsing remitting multiple sclerosis.

The applicant for this medicinal product is Biogen Netherlands B.V.

Vumerity will be available as 231 mg gastro-resistant capsules. The active substance of Vumerity is diroximel fumarate (ATC code: L04AX). The mechanism by which diroximel fumarate works in multiple sclerosis is not fully understood. Diroximel fumarate acts via the major active metabolite, monomethyl fumarate (MMF).

This marketing authorisation application is based on a pharmacologic bridging approach to the authorised product dimethyl fumarate (Tecfidera). Bioequivalence to dimethyl fumarate has been shown for the active moiety MMF. Therefore, the benefits of Vumerity are expected to be the same as those of Tecfidera, including the reduction of the risk of the appearance of relapses and inflammatory lesions in the central nervous system.

Similarly to Tecfidera, the most common side effects are flushing and gastrointestinal events.

The full indication is:

> Vumerity is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (see section 5.1 for important information on the populations for which efficacy has been established).

Vumerity should be initiated under supervision of a physician experienced in the treatment of multiple sclerosis.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.