21 March 2024
EMA/CHMP/107054/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dimethyl fumarate Mylan

Dimethyl fumarate

On 21 March 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dimethyl fumarate Mylan, intended for the treatment of multiple sclerosis. The applicant for this medicinal product is Mylan Ireland Limited.

Dimethyl fumarate Mylan will be available as 120 mg and 240 mg gastro-resistant hard capsules. The active substance of Dimethyl fumarate Mylan is dimethyl fumarate, an immunosuppressant (ATC code: L04AX07). Dimethyl fumarate acts primarily by activating the Nrf2 transcriptional pathway, which reduces inflammation and modulates the activity of immune cells, thereby protecting the cells of the central nervous system from damage.

Dimethyl fumarate Mylan is a generic of Tecfidera, which has been authorised in the EU since 30 January 2014. Studies have demonstrated the satisfactory quality of Dimethyl fumarate Mylan, and its bioequivalence to the reference product Tecfidera. A question and answer document on generic medicines can be found here.

The full indication is:

> Dimethyl fumarate Mylan is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).

Treatment should be initiated under the 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 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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