24 February 2022
EMA/CHMP/102832/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dimethyl fumarate Mylan

dimethyl fumarate

On 24 February 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 Dimethyl fumarate Mylan, intended for the treatment of adult patients with relapsing remitting 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 immunomodulating agent (ATC code: L04AX07). It primarily acts by triggering the activation of the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) transcriptional pathway.

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 patients with relapsing remitting multiple sclerosis.

The treatment with Dimethyl fumarate Mylan should be initiated under the supervision of a physician experienced in the treatment of the disease.

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

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