15 December 2022
EMA/CHMP/922592/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dimethyl fumarate Accord

dimethyl fumarate

On 15 December 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 Accord, intended for the treatment of multiple sclerosis. The Applicant for this medicinal product is Accord Healthcare S.L.U.

Dimethyl fumarate Accord will be available as 120 mg and 240 mg gastro-resistant hard capsules. The active substance of Dimethyl fumarate Accord is dimethyl fumarate, an immunosuppressant (ATC code: L04AX07). It primarily acts by triggering the activation of the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) transcriptional pathway.

Dimethyl fumarate Accord 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 Accord, 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 Accord 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 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.

Medicinal product no longer authorised

[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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