24 February 2022
EMA/CHMP/103073/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dimethyl fumarate Polpharma

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 Polpharma, intended for the treatment of adult patients with relapsing remitting multiple sclerosis.

The applicant for this medicinal product is Zaklady Farmaceutyczne Polpharma S.A.

Dimethyl fumarate Polpharma will be available as 120 mg and 240 mg gastro-resistant hard capsules. The active substance of Dimethyl fumarate Polpharma 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 Polpharma 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 Polpharma 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 Polpharma is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis.

The treatment with Dimethyl fumarate Polpharma 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