



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Tecfidera Dimethyl fumarate

On 21 March 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tecfidera 120 mg and 240 mg, gastro-resistant hard capsules, intended for the treatment of adult patients with relapsing remitting multiple sclerosis.

The applicant for this medicinal product is Biogen Idec Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The approved indication is: "treatment of adult patients with relapsing remitting multiple sclerosis".

The active substance of Tecfidera is dimethyl fumarate, a nervous system drug (N07XX09), that primarily acts by triggering the activation of the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) transcriptional pathway.

The benefits with Tecfidera are its ability to reduce the number of relapses in patients with relapsing-remitting multiple sclerosis. The most common side effects are flushing and gastrointestinal events (e.g. diarrhoea, nausea and abdominal pain).

A pharmacovigilance plan for Tecfidera will be implemented as part of the marketing authorisation.

Treatment with Tecfidera 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.



The CHMP, on the basis of quality, safety and efficacy data submitted, considered there to be a favourable benefit-risk balance for Tecfidera and therefore recommends the granting of the marketing authorisation.

Update

Without prejudice to the conclusions reached by the CHMP in March 2013 on the favourable benefit-risk balance of Tecfidera, the decision making process at the European Commission was put on hold at the request of the applicant. Subsequently, in September 2013, the applicant requested a CHMP assessment on whether the active substance of Tecfidera, dimethyl fumarate, qualifies as a new active substance under Directive 2001/83/EC.

The CHMP has now completed its assessment and considers that dimethyl fumarate is different from Fumaderm². Therefore, the active substance of Tecfidera, dimethyl fumarate, is a new active substance. This conclusion is based on the review of the scientific evidence, and in line with clarification provided by the European Commission that:

- i) a new active substance under Directive 2001/83/EC is a chemical substance not previously authorised as a medicinal product in the European Union (Annex I to the Notice to applicants Volume 2A, Procedures for marketing authorisation, Chapter 1, Marketing authorisations, June 2013) and,
- ii) dimethyl fumarate is part of the medicinal product Fumaderm authorised in 1994 in Germany, but it has not been previously authorised as a medicinal product in the European Union.

The outcome of the CHMP assessment will now be sent to the European Commission for the completion of the decision making process.

² Fumaderm is composed of dimethyl fumarate, calcium salt of ethyl fumarate, magnesium salt of ethyl hydrogen fumarate and zinc salt of ethyl hydrogen fumarate