



22 April 2022
EMA/CHMP/691024/2021 Rev.2
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tecfidera

dimethyl fumarate

On 22 April 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Tecfidera.² The marketing authorisation holder for this medicinal product is Biogen Netherlands B.V.

The CHMP adopted an extension to the existing indication as follows:

Treatment of paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).

For information, the full indications for Tecfidera will be as follows³:

Tecfidera is indicated for the treatment of adult **and paediatric** patients ~~with relapsing remitting multiple sclerosis (see section 5.1 for important information on the populations for which efficacy has been established)~~ **aged 13 years and older with relapsing remitting multiple sclerosis (RRMS)**.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after a decision on this change to 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

² The CHMP had initially adopted an opinion on 27 January 2022. Following a re-examination of the initial opinion at the request of the marketing authorisation holder, the CHMP readopted its opinion on 22 April 2022.

³ New text in bold, removed text as strikethrough

