



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): dimethyl fumarate (multiple sclerosis)

Procedure No. EMEA/H/C/PSUSA/00010143/202103

Period covered by the PSUR: 26 March 2019 To: 26 March 2021



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for dimethyl fumarate (multiple sclerosis), the scientific conclusions of CHMP are as follows:

In view of available data on alopecia from spontaneous reports including in 2190 (consumer reports)/760 (HCP reports) cases with a close temporal relationship, a positive de-challenge and/or re-challenge (consumer report: 242 and 10; HCP reports: 35 and 4, respectively) and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between dimethyl fumarate and alopecia is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing dimethyl fumarate should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for dimethyl fumarate (multiple sclerosis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dimethyl fumarate (multiple sclerosis) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.