



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/557312/2020
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 (psoriasis)

Procedure No. EMEA/H/C/PSUSA/00010647/202006

Period covered by the PSUR: from 24 December 2019 to 23 June 2020



Scientific conclusions

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

Cumulative up to June 2020, 4 cases of herpes zoster (1 serious) were retrieved from the MAH safety database. Despite the low numbers, in view of available data from spontaneous reports including cases with a temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between Skilarence and herpes zoster is at least a reasonable possibility. The PRAC therefore proposes that the product information is amended accordingly to reflect this ADR.

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 (psoriasis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dimethyl fumarate (psoriasis) 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.