



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/154380/2025
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): dabrafenib

Procedure No. EMEA/H/C/PSUSA/00010084/202405

Period covered by the PSUR: 27 August 2022 to 29 May 2024



Scientific conclusions

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

In view of available data on risk from the literature and spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between dabrafenib and probable Vogt-Koyanagi-Harada (VKH)-like uveitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing dabrafenib should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for dabrafenib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dabrafenib 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.