Amsterdam, 29 January 2026
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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): dabrafenib

Procedure No. EMEA/H/C/PSUSA/00010084/202505

Period covered by the PSUR: 30 May 2024 to 29 May 2025

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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 events of radiation recall and sensitisation from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, localisation of the event within the irradiated field and in view of a plausible mechanism of action, the PRAC considers a causal relationship between dabrafenib and potentiation of radiation toxicity 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.