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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): ruxolitinib (for non-segmental vitiligo)

Procedure No. PSUSA/00011052/202509

Period covered by the PSUR: 21 September 2024 to 20 September 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ruxolitinib (for non-segmental vitiligo), the scientific conclusions of PRAC are as follows:

In view of available data on 'herpes zoster' from clinical trials, spontaneous reports including cases with a close temporal relationship, a positive de-challenge, the PRAC considers a causal relationship between ruxolitinib cream and 'herpes zoster' is at least a reasonable possibility. The PRAC concluded that the product information of products containing ruxolitinib (for non-segmental vitiligo) 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

On the basis of the scientific conclusions for ruxolitinib (for non-segmental vitiligo) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ruxolitinib (for non-segmental vitiligo) is unchanged subject to the proposed changes to the product information

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