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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): dostarlimab

Procedure No. PSUSA/00010931/202504

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

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for dostarlimab, the scientific conclusions of PRAC are as follows:

In view of available data on Stevens-Johnson syndrome from spontaneous reports and in view of a plausible mechanism of action, the PRAC Rapporteur considers that a causal relationship between dostarlimab and Stevens-Johnson syndrome (SJS) is at least a reasonable possibility. The PRAC concluded that the product information of products containing dostarlimab 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 dostarlimab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing dostarlimab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.