14 November 2024
EMA/19434/2025
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): risankizumab

Procedure No. EMEA/H/C/PSUSA/00010765/202403

Period covered by the PSUR: 26 March 2023 to 25 March 2024

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Scientific conclusions

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

In view of available data on anaphylaxis from spontaneous reports, including in 6 cases with a close temporal relationship, the PRAC considers a causal relationship between risankizumab and anaphylaxis is at least a reasonable possibility. The PRAC concluded that the product information of products containing risankizumab 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 risankizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing risankizumab 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.