10 November 2022
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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): risankizumab

Procedure No. EMEA/H/C/PSUSA/00010765/202203

Period covered by the PSUR: 25 March 2021 to 25 March 2022

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Scientific conclusions

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

In view of available data on rash and urticaria from spontaneous reports including in respectively 30 and 118 cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between Risankizumab and rash and urticaria is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing risankizumab should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.