EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): voclosporin

Procedure No. EMEA/H/C/PSUSA/00011020/202401

Period covered by the PSUR: 22 July 2023 to 21 January 2024

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Scientific conclusions

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

In view of available data on hypersensitivity from clinical trial, post-marketing reports including 10 cases with a close temporal relationship, 6 cases of positive de-challenge and 2 cases of positive re-challenge, the PRAC considers a causal relationship between voclosporin and hypersensitivity is at least a reasonable possibility.

In view of available data on pneumonia from clinical trials, post-marketing reports including 24 cases with a close temporal relationship, and in view a plausible mechanism of action, the PRAC considers a causal relationship between voclosporin and pneumonia is at least a reasonable possibility.

In view of available data on mouth ulceration from clinical trials, post-marketing reports including 11 cases with a close temporal relationship, the PRAC considers a causal relationship between voclosporin and mouth ulceration is at least a reasonable possibility.

The PRAC concluded that the product information of products containing voclosporin 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 voclosporin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing voclosporin 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.