18 September 2025
EMADOC-1700519818-2639887
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. PSUSA/00011020/202501

Period covered by the PSUR: 6 months to 20 January 2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 fatigue from clinical trials, spontaneous reports including in 237 cases with a close temporal relationship, 10 cases with positive de-challenge, the PRAC considers a causal relationship between voclosporin and fatigue 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.