30 January 2025
EMA/23738/2025
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): vedolizumab

Procedure No. EMEA/H/C/PSUSA/00010186/202405

Period covered by the PSUR: 19/05/2021 To: 19/05/2024

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Scientific conclusions

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

In view of available data on liver injury from clinical trials, the literature, spontaneous reports including cases in a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between vedolizumab, and liver enzyme increased and hepatitis is at least a reasonable possibility.

Hypersensitivity reactions occurred after switching from SC to IV administration in 8 spontaneous cases reported during the period of this PSUR and 4 relevant publications were identified as part of a French national survey on vedolizumab, carried out by a pharmacovigilance regional centre. These cases reported adverse events related to immediate hypersensitivity reactions when IV vedolizumab was reintroduced after SC treatment. Six were serious cases of which one case of anaphylactic reaction, and 2 non-serious. The PRAC considers that in the existing warning on hypersensitivity in 4.4. of the SmPC of the i.v. formulation it should be mentioned that cases occurred during switching to strengthen the existing warning that patients need to be observed for signs of hypersensitivity reactions.

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