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): ofatumumab

Procedure No. PSUSA/00010927/202509

Period covered by the PSUR: 1 year to 25 September 2025

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Scientific conclusions

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

In view of available data on increase of hepatic function tests from spontaneous reports, the PRAC considers that a causal relationship between ofatumumab and liver enzymes increase is at least a reasonable possibility. The PRAC concluded that the product information of Kesimpta 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 ofatumumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ofatumumab 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.