22 June 2023
EMA/374564/2023
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): tixagevimab / cilgavimab (Evusheld)

Procedure No. EMEA/H/C/PSUSA/00010992/202211

Period covered by the PSUR:
14/05/2022 To: 13/11/2022

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Scientific conclusions

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

In view of available data on hypersensitivity reactions from spontaneous reports including in some cases a plausible temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tixagevimab / cilgavimab and anaphylaxis. The PRAC concluded that the product information of products containing tixagevimab / cilgavimab 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 tixagevimab / cilgavimab (Evusheld) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tixagevimab / cilgavimab (Evusheld) 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.