



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2022
EMA/CHMP/236426/2022
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): remimazolam

Procedure No. EMEA/H/C/PSUSA/00010924/202107

Period covered by the PSUR: 22/01/2022 To: 22/07/2022



Scientific conclusions

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

In view of available data on anaphylactic reaction from the literature and spontaneous reports including in some cases a close temporal relationship, the PRAC considers a causal relationship between remimazolam and anaphylactic reaction is at least a reasonable possibility. The PRAC concluded that the product information of products containing remimazolam 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 remimazolam the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing remimazolam 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.