15 September 2022
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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): remimazolam

Procedure No. EMEA/H/C/PSUSA/00010924/202201

Period covered by the PSUR: 23/07/2021 to 22/01/2022

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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 vascular access site occlusion from the literature and spontaneous reports, the PRAC considers that the product information should be strengthened to ensure healthcare professionals are adequately informed of the potential risk of vascular access site occlusion when remimazolam is administered with incompatible fluids. 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.