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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): isatuximab

Procedure No. EMEA/H/C/PSUSA/00010851/202103

Period covered by the PSUR: 01/09/2020 To: 01/03/2021

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Scientific conclusions

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

In view of available data on a medication error case from spontaneous sources,the PRAC considers that the product information of products containing isatuximab 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 isatuximab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing isatuximab 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.