13 October 2022
EMA/29807/2023
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): isatuximab

Procedure No. EMEA/H/C/PSUSA/00010851/202203

Period covered by the PSUR: 01 March 2021 to 01 March 2022

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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 Tumour Lysis Syndrome from clinical trials, the literature, spontaneous reports including in one case a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between Isatuximab and tumour lysis syndrome is at least a reasonable possibility. The PRAC concluded 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.