



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/403185/2021
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): rituximab

Procedure No. EMEA/H/C/PSUSA/00002652/202011

Period covered by the PSUR: 17 November 2019 to 17 November 2020



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for rituximab, the scientific conclusions of the CHMP are as follows:

In view of available data on the risk of malignancy from clinical trials, the literature, spontaneous reports and observational post-authorisation safety studies indicating no increased risk of malignancy in the autoimmune indications, the PRAC considers amendments to the product information are warranted.

Moreover, based on evidence from literature articles of rituximab excretion into human breast milk, the PRAC considers amendments to the product information are warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for rituximab the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing rituximab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.