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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): ibritumomab tiuxetan

Procedure No. EMEA/H/C/PSUSA/00001704/201702

Period covered by the PSUR: 01 March 2014 – 28 February 2017

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Scientific conclusions

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

The PRAC considered that the information on myelodysplastic syndrome (MDS)/ acute myeloid leukaemia (AML) in section 4.8 of the SmPC should be further clarified. It should be specified that the frequency 'common' attributed to this adverse drug reaction has been derived from a study on consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. The description of the ADR in the same section of the SmPC should be amended accordingly to clarify which statements relate to each of the two indications (consolidation therapy in follicular lymphoma vs relapsed or refractory Non-Hodgkin's lymphoma (NHL)). The Package Leaflet should also 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 ibritumomab tiuxetan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ibritumomab tiuxetan 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.