28 February 2019
EMA/302553/2019
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): carfilzomib

Procedure No. EMEA/H/C/PSUSA/00010448/201807

Period covered by the PSUR: 20 January 2018 – 19 July 2018

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Scientific conclusions

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

A search of MAH's databases and Eudravigilance identified high number of cases of Cytomegalovirus (CMV) infections reported in clinical trials and in post-marketing settings. In addition, recent studies have shown that patients with multiple myeloma receiving novel agents are at increased risk for CMV reactivation. Based on the high number of cases and a potential class effect/plausible mechanism, the product information should be updated to include Cytomegalovirus infection (frequency: uncommon).

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 carfilzomib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing carfilzomib 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.