19 November 2015
EMA/747320/2015
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: bortezomib

Procedure No. EMEA/H/C/PSUSA/00000424/201504

Period covered by the PSUR: 26 April 2014 - 25 April 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

The MAH conducted a cumulative review of all cases reporting preferred terms from the gastrointestinal obstruction Standardised MedDRA Query (SMQ) for bortezomib as part of a signal assessment for “intestinal obstruction”. Excluding ileus and oesophageal and gastric events, the search retrieved 34 cases without confounding factors. Of these cases, 13 described a positive dechallenge and 1 described a positive rechallenged. The MAH concluded that intestinal obstruction with the frequency uncommon is associated with the use of bortezomib in patients with Multiple Myeloma. “Gastrointestinal obstruction (inc ileus)” is already included in the product information (PI) of Velcade. However the PRAC was of the view that the MedDRA PT reported as ADR under the high level term “gastrointestinal obstruction” providing more information on the localisation of the obstruction (small intestinal obstruction) should be specified as well in the SmPC. This was considered covered by “poor movement of the intestines (including blockage)” currently listed in the package leaflet, therefore no update of the PL was considered necessary.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing bortezomib were warranted.

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

Grounds for the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for bortezomib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bortezomib is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.