22 August 2014
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Committee for Medicinal Products for Human Use (CHMP)

Victrelis

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

International non-proprietary name: boceprevir

Procedure No.: EMEA/H/C/002332/PSUV/0028

Period covered by the PSUR: 13 May 2013 to 11 November 2013

Medicinal product no longer authorised

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Scientific conclusions

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

In response to the PRAC assessment of the previous PSUR (PSUR 4), the MAH provided an evaluation of the available literature and of the MAH's clinical and post-marketing databases on predictive factors of severe adverse events and poor outcomes in patients with cirrhosis. After consideration of the results of observational studies from the literature, the MAH proposed to update the SmPC to include that patients with advanced liver disease are at higher risk of experiencing severe complications and that low platelet counts and hypoalbuminemia were identified as predictive factors for severe complications. This update of the product information was supported by the PRAC with some amendments to the wording.

In responses to the PRAC assessment of the previous PSUR (PSUR 4), the MAH discussed the signal on infection/sepsis and potential risk factors associated with these events. The MAH proposed to update the SmPC to include low platelet counts and hypoalbuminemia as predictive factors of severe infections and to cover the poor safety profile of Victrelis in combination with peginterferon alfa and ribavirin and the need for close monitoring. This update of the product information was supported by the PRAC with some amendments to the wording.

Following the PRAC assessment of the previous PSUR (PSUR 4), the MAH was requested within this PSUR to discuss a proposal to update the SmPC with regards to co-administration of boceprevir with tamsulosin and doxazosin. The MAH therefore proposed to update the SmPC to reflect that concomitant use of boceprevir with tamsulosin and doxazosin is not recommended. This update of the product information was supported by the PRAC.

Therefore, in view of available data, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Victrelis, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance BOCEPREVIR 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.

Medicinal product no longer authorised