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Committee for Medicinal Products for Human Use (CHMP)

Betmiga

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

International non-proprietary name: mirabegron

Procedure No. EMEA/H/C/002388/PSUV/0007

Period covered by the PSUR: 01.01.2013 -30.06.2013

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Scientific conclusions

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

The signal on urinary retention has been evaluated in the context of this PSUR. A causal association between urinary retention and mirabegron cannot be substantiated by available data. However, due to confounding factors in the patient population some populations may be at risk of urinary retention, mainly patients treated with antimuscarinic and patients with BOO. Therefore, in view of available data regarding urinary retention, the PRAC considered that changes to the product information were warranted.

After the evaluation of this signal, the SmPC is recommended to be updated with the inclusion of a warning in section 4.4. The package leaflet is to be amended accordingly. In addition, urinary retention has been added in the RMP as important potential risk.

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 Betmiga, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance mirabegron is favourable subject to the proposed changes to the product information.

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