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EMA/CHMP/109669/2015
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/0015

Period covered by the PSUR: 01 January 2014 – 30 June 2014

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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:

After the evaluation of the signal “nausea and vomiting”, the Marketing Authorisation Holder (MAH) has updated its Company Core Datasheet (CCDS) after the data lock point (DLP) of this PSUR to include nausea in section 4.8. The MAH proposed to include nausea also in section 4.8 of the SmPC and to update the PL accordingly. Taking into account the guideline of SmPC and regarding the frequency of nausea observed in clinical trials (1.4%), the PRAC agreed that the frequency of nausea should be “common”.

Therefore, in view of available data regarding nausea, 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 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.

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