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EMA/CHMP/778367/2014
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/0013

Period covered by the PSUR: 1 July 2013 – 31 December 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 MAH presented in the PSUR information about 42 cases retrieved after a search using the SMQ of angioedema in the MAH's database. Based on an additional analysis in the Eudravigilance database, the PRAC identified four cases reported Angioedema as PT, and found 12 cases reporting lip swelling, 9 cases reporting swelling face, 8 cases reporting swollen tongue and 4 cases reporting pharyngeal oedema. Lip oedema, Lip swelling and swollen tongue meet the disproportionality criteria. The current mirabegron company core safety information (CCSI) does not list angioedema specifically as an adverse drug reaction in SmPC Section 4.8 "Undesirable Effects". However, the terms Urticaria and rash are listed as uncommon ADRs. In addition, lip oedema and eyelid oedema are included as rare adverse reactions. The PRAC noted that angioedema has not been observed in clinical trials so far.

After analysing the narrative of the cases identified and taking into account the fact that hypersensitivity is an important identified risk in the RMP of mirabegron and urticaria, lip oedema, eyelid oedema are listed as adverse reactions in the SmPC, the PRAC considers that changes to the product information are warranted to include angioedema with the frequency category "rare" in section 4.8 of the SmPC and relevant section of the PL.

Therefore, in view of available data regarding angioedema, 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(s) should be varied.