EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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: mirabegron

Procedure No. EMEA/H/C/PSUSA/00010031/201412

Period covered by the PSUR: 1 July 2014 – 31 December 2014

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Scientific conclusions

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

Considering the cumulative data available regarding hypertension, the several reports of hypertensive crisis in which it is not possible to exclude a possible relationship with mirabegron, the cases of cerebrovascular events and cardiac events (such cases of cardiac ischaemia and cardiac failure) that also reported hypertension, the existing warning on hypertension in section 4.4 of the SmPC should be updated. The use in severe uncontrolled hypertensive patients should be included as a contraindication in section 4.3. The package leaflet should be updated accordingly.

These are new recommendations for preventing an adverse effect including the introduction of a new contraindication. This change to the use of this medicine warrants active dissemination of the information via a Direct Healthcare Professional Communication (DHPC), which has been agreed by the PRAC.

In addition, taking into account the high number of cases of urinary retention reported, most of them considered as serious and most of them with a plausible temporal relationship, urinary retention should be listed in the section 4.8 of the SmPC. The package leaflet should be updated accordingly.

And finally, considering the number or reports of insomnia, the cases with a compatible time relationship and dechallenge positive and one of them with rechallenge positive, insomnia should be included in section 4.8 of the SmPC and in the package leaflet.

Therefore, in view of available data regarding mirabegron, 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 mirabegron the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing mirabegron is favourable subject to the proposed changes to the product information

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