18 October 2012
EMA/CHMP/551730/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Betmiga

mirabegron

On 18 October 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Betmiga, 25 mg, 50 mg, prolonged-release film-coated tablet intended for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in patients with overactive bladder (OAB) syndrome.

The applicant for this medicinal product is Astellas Pharma Europe B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Betmiga is mirabegron, an urological (ATC Code: G04BD12).

Mirabegron is a selective agonist for human beta 3-adrenoceptor (beta 3-AR) which is dominant in the human detrusor muscle. Activation of the beta-AR in the bladder trigone facilitates urine storage through flattening and lengthening of the bladder base.

The benefits with Betmiga are its ability to reduce the number of daily micturitions and incontinence episodes. The main safety concern relates to cardiovascular safety. Mirabegron at the proposed 50 mg dose shows a modest increment of pulse rate and blood pressure (1 bpm and ≤1 mm Hg compared with placebo).

A pharmacovigilance plan for Betmiga will be implemented as part of the marketing authorisation.

The approved indication is: "Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome." Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Betmiga and therefore recommends the granting of the marketing authorisation.