27 June 2024
EMA/CHMP/30239/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Betmiga

mirabegron

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Betmiga. The marketing authorisation holder for this medicinal product is Astellas Pharma Europe B.V.

The CHMP adopted a new indication for prolonged-release tablets to include treatment of children and adolescents with neurogenic detrusor overactivity (NDO). For information, the full indications for Betmiga prolonged-release tablets will therefore be as follows:[2]

> Overactive bladder in adults
>
> Betmiga prolonged-release tablets are indicated for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.
>
> **Neurogenic detrusor overactivity in the paediatric population**
>
> **Betmiga prolonged-release tablets are indicated for treatment of neurogenic detrusor overactivity (NDO) in paediatric patients aged 3 to less than 18 years.**

The CHMP also adopted a new pharmaceutical form (granules for prolonged-release oral suspension) associated with the new indication. The full indication for Betmiga granules for prolonged-release oral suspension is:[2]

> **Betmiga granules for prolonged-release oral suspension is indicated for treatment of neurogenic detrusor overactivity (NDO) in paediatric patients aged 3 to less than 18 years.**

The new formulation may be used in paediatric patients under 35 kg.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report

[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
[2] New text in bold

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(EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.