25 April 2024
EMA/CHMP/159701/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Obgemsa

vibegron

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Obgemsa, intended for the symptomatic treatment of adults with overactive bladder (OAB) syndrome. Symptoms of OAB syndrome may include the urge to urinate, increased micturition frequency and urgency incontinence.

The applicant for this medicinal product is Pierre Fabre Medicament.

Obgemsa will be available as 75 mg film-coated tablet. The active substance of Obgemsa is vibegron, a urological drug for urinary frequency and incontinence (ATC code: G04BD15). Vibegron is a selective human beta 3-adrenoceptor (beta 3-AR) agonist. By activating the beta 3-AR in the bladder, vibegron flattens and lengthens the base of the bladder, facilitating urine storage.

The benefits of Obgemsa are its ability, after 12 weeks of treatment, to reduce the number of daily micturitions and incontinence episodes in patients with overactive bladder syndrome, compared to placebo. The effects of Obgemsa are maintained after 52 weeks of treatment. The most common side effects with Obgemsa are headache, diarrhoea, nausea (feeling sick), constipation, urinary tract infection (infection of structures that carry urine), residual urine volume increased (an increase in the amount of urine left in the bladder after a voluntary urination).

The full indication is:

Obgemsa is indicated in symptomatic treatment of 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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