www.scottishmedicines.org.uk

Advice document
SMC2696

vibegron film-coated tablets (Obgemsa®)

Pierre Fabre

08 November 2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

vibegron (Obgemsa®) is accepted for use within NHSScotland.

Indication under review: symptomatic treatment of adult patients with overactive bladder (OAB) syndrome.

Vibegron offers an additional treatment choice in the therapeutic class of beta-3 adrenergic receptor agonists in this setting.

Vice Chair
Scottish Medicines Consortium

Published 09 December 2024

1. Clinical Context

1.1. Medicine background

Vibegron is a beta-3-adrenergic receptor agonist licensed for the symptomatic treatment of adult patients with overactive bladder (OAB) syndrome. It is administered orally, and the recommended dose is 75 mg once daily. [1]

1.2. Relevant comparator

Mirabegron (Betmiga®) is another beta-3 adrenergic receptor agonist within the same therapeutic class as vibegron. Mirabegron is accepted for use within NHSScotland for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome (SMC862/13).

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

The licensed dose of vibegron in the UK is 75 mg; this was the dose given in the phase 3 international placebo- and active-controlled EMPOWUR study, and the long-term extension EMPOWUR-EXT study.[2, 3] EMPOWUR included 1,518 patients (up to 15% of patients could be male) aged 18 years or older with a history of OAB. Patients were randomised in a 5:5:4 ratio to double-blind treatment with vibegron 75 mg, placebo or extended-release tolterodine 4 mg once daily for 12 weeks. The co-primary endpoints were change from baseline to week 12 in: the average daily number of micturitions for each patient; and the average daily number of urge urinary incontinence episodes for each patient with wet OAB (that is urinary urgency with incontinence). Compared with placebo, vibegron provided statistically significant reductions in micturitions, urgency episodes and urge incontinence, and increased the volume per micturition. Efficacy responses to vibegron in patients with prior OAB pharmacotherapy (anticholinergic or beta-3 adrenoceptor agonist) were similar to treatment-naive patients. Treatment was well tolerated with an acceptable safety profile.[2] Patients who completed 12 weeks of treatment were eligible to enter the long-term extension study (EMPOWUR-EXT); 506 patients continued on the active treatment to which they were originally randomised or if originally assigned to placebo were re-randomised in a 1:1 ratio to double-blind vibegron or tolterodine until week 52. The primary outcome was safety, measured by incidence of adverse events, but efficacy measures were included as secondary outcomes. Results were consistent with the 12-week study.[3]

The company has provided indirect evidence to compare the licensed 75 mg dose of vibegron with mirabegron, the most relevant comparator. The company commissioned and provided results from an unpublished indirect treatment comparison (ITC) which compared efficacy and safety outcomes from ten studies, including the two pivotal phase 3 studies for vibegron (EMPOWUR and EMPOWER-EXT) and 8 studies that used mirabegron 50 mg as an intervention

in patients with OAB syndrome.[4] Additionally, three published ITCs were referenced which compared the efficacy and safety of vibegron 75 mg, mirabegron 25/50 mg and anticholinergics in the treatment of OAB syndrome.[5-7] Overall, the results from the ITCs provide assurance that vibegron 75 mg is at least comparable with mirabegron and did not indicate any difference in serious adverse events between the treatments.

Two small, randomised, open-label, parallel studies compared vibegron 50 mg directly with mirabegron 50 mg daily for 12 weeks. This reflects the licensed dose in the UK for mirabegron, but not vibegron. Both studies showed no statistical differences between vibegron and mirabegron in efficacy outcomes, including overactive bladder symptom scores (OABSS), daytime and nighttime frequency, urgency urinary incontinence, and urgency episodes. In both studies, the population was postmenopausal women with treatment-naïve OAB syndrome and is therefore narrower than the indication. The studies were also conducted exclusively in Japan, which further limits the generalisability of results.[8, 9]

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment

The company estimated that there would be 28,936 patients eligible for treatment with vibegron in year 1, and 29,246 patients in year 5.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

References

1. Medicines & Healthcare products Regulatory Agency. Pierre Fabre Limited. Vibegron tablets (Obgemsa®) Summary of product characteristics. PLGB 00603/0250 Available at https://products.mhra.gov.uk/ Last updated July 2024.

2. Staskin D, Frankel J, Varano S, Shortino D, Jankowich R, Mudd PN, Jr. International Phase III, Randomized, Double-Blind, Placebo and Active Controlled Study to Evaluate the Safety and Efficacy of Vibegron in Patients with Symptoms of Overactive Bladder: EMPOWUR.

3. Staskin D, Frankel J, Varano S, Shortino D, Jankowich R, Mudd PN, Jr. Once-Daily Vibegron 75 mg for Overactive Bladder: Long-Term Safety and Efficacy from a Double-Blind Extension Study of the International Phase 3 Trial (EMPOWUR).

4. Pierzchala P, Brown R. Indirect Treatment Comparison of Vibegron and Mirabegron for Overactive Bladder.

5. He W, Zhang Y, Huang G, Tian Y, Sun Q, Liu X. Efficacy and safety of vibegron compared with mirabegron for overactive bladder: A systematic review and network meta-analysis.

6. Kennelly M, Wielage R, Shortino D, Thomas E, Mudd PN, Jr. Long-term efficacy and safety of vibegron versus mirabegron and anticholinergics for overactive bladder: a systematic review and network meta-analysis.

7. Kennelly MJ, Rhodes T, Girman CJ, Thomas E, Shortino D, Mudd PN, Jr. Efficacy of Vibegron and Mirabegron for Overactive Bladder: A Systematic Literature Review and Indirect Treatment Comparison. Adv Ther. 2021;38(11):5452-64. Epub 20210918.

8. Kinjo M, Masuda K, Nakamura Y, Miyakawa J, Tambo M, Fukuhara H. Comparison of Mirabegron and Vibegron in Women With Treatment-Naive Overactive Bladder: A Randomized Controlled Study.

9. Sato H, Otsuka S, Tsukada S. Mirabegron versus vibegron in previously untreated female patients with overactive bladder: A randomized, single-clinic, open-label trial.

This assessment is based on data submitted by the applicant company up to and including 30 May 2024.

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.