BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

BETMIGA (mirabegron), urinary antispasmodic

Insufficient clinical benefit to justify its inclusion on the list of reimbursable products for overactive bladder syndrome due to a poorly established efficacy/adverse effects ratio.

Main points

- BETMIGA has Marketing Authorisation in the symptomatic treatment of urinary urgency and increased urinary frequency and/or urge incontinence that may occur in adults with overactive bladder syndrome (OAB).
- Its efficacy is low compared with placebo. A study was unable to demonstrate the non-inferiority of BETMIGA compared with VESICARE (solifenacin) in terms of mean number of micturitions per day.
- The cardiovascular tolerance of BETMIGA is still being monitored.

Therapeutic use

- Anticholinergic drug treatment for urinary urgency and increased urinary frequency or urge incontinence can be offered as first-line therapy or after the failure of behavioural and/or rehabilitation therapy.
- **Role of the proprietary medicinal product in the therapeutic strategy**
  Given its poorly established efficacy/adverse effects ratio, BETMIGA has no role in the therapeutic strategy for increased urinary frequency and/or urinary urgency and/or urge incontinence in patients with overactive bladder.

Clinical data

- A non-inferiority study compared mirabegron 50 mg/day to solifenacin 5 mg/day in patients with overactive bladder (OAB), for whom other anticholinergics (except solifenacin) were considered ineffective by the patients. The dosage of the solifenacin was not optimal because the Marketing Authorisation allows, if necessary, a dose increase to 10 mg/day of solifenacin once daily. A total of 936 patients received mirabegron and 934 received solifenacin for 12 weeks. The mean number of micturitions per day at baseline was 11.6 in the mirabegron group and 11.4 in the solifenacin group. The mean number of micturitions per day between baseline and end of treatment was reduced in both groups: by 2.95 in the mirabegron group and 3.13 in the solifenacin group, i.e. a difference of 0.18 (95% CI [-0.42; 0.006]) between the two treatment groups; however, this did not demonstrate the non-inferiority of mirabegron compared with solifenacin (non-inferiority demonstrated if the lower threshold of the 95% CI was above -0.20). Clinical symptoms such as increased urinary frequency and urinary urgency were not evaluated. The lack of demonstration of a non-inferiority of mirabegron compared with solifenacin does not allow any conclusion to be drawn about their relative efficacy.
- In the study populations, which excluded patients unsatisfied with their prior anticholinergic treatment (other than solifenacin) due to tolerance, mirabegron had a lower incidence of dry mouth (3.1% vs 5.8%) compared with solifenacin. Constipation was reported with a similar percentage in both patient groups (2.2% for mirabegron vs 2.5% for solifenacin).

Benefit of the medicinal product

- The actual benefit* of BETMIGA is insufficient to justify reimbursement by National Health Insurance.
- Does not recommend inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 11 October 2017 (CT-16034) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.