HAUTE AUTORITÉ DE SANTÉ

UROLOGY
New medicinal product
July 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

NOCDURNA (desmopressin), vasopressin analogue

Insufficient clinical benefit in the treatment of nocturia associated with idiopathic nocturnal polyuria in the absence of any role in the therapeutic strategy

Main points

- NOCDURNA has Marketing Authorisation in treatment of nocturia in adults, when it is associated with idiopathic nocturnal polyuria.
- The impact on quality of life has not been demonstrated.
- The efficacy on the reduction of urination, compared with placebo, was low and without clinical relevance. It was established short-term in patients with low severity. The transferability to an older population with greater severity is not assured.
- There is a risk of severe hyponatraemia due to drug interactions with desmopressin in elderly patients on multiple medications.

Therapeutic strategy

- Dietary and behavioural changes should be suggested in all patients with nocturia associated with idiopathic nocturnal polyuria.
- In adults, symptomatic treatment with desmopressin may be suggested, with the knowledge that it is contraindicated in case of known history of hyponatraemia, polydipsia or potomania, heart failure or another condition associated with a fluid overload sufficient to require diuretic treatment, and in case of moderate to severe kidney failure. Desmopressin should be used with caution in patients with fluid and/or electrolyte imbalance.
- **Role of the medicinal product in the therapeutic strategy**

  Given a low efficacy and lack of clinical relevance when compared with placebo, and the severe risk of hyponatraemia due to drug interactions in elderly patients on multiple medications, NOCDURNA has no role in the treatment of nocturia associated with idiopathic nocturnal polyuria.

Clinical data

- The efficacy was established in two controlled, randomised, double-blind studies: one study compared 25 µg/day of desmopressin per os with placebo in 268 women; the other study compared 50 µg/day and 75 µg/day of desmopressin with placebo in 395 men.
  The patients included, of a median age of 62 years, had nocturia defined as a mean of night-time urination 2 and more times per night; polyuria was also observed in 89% of women and 87% of men.
  After 3 months of treatment, about twice as many patients were treatment responders (primary endpoint), i.e. a reduction > 33% in the number of urinations, in the desmopressin groups compared with the placebo groups (p=0.0061 in the study conducted in women and p=0.0009 in the study conducted in men). Similarly, the decrease in the adjusted mean number of night-time urinations from baseline was higher in the desmopressin groups, with a difference of - 0.22 [-0.42; -0.02], p = 0.028 in women and - 0.37 [-0.57; -0.17], p = 0.0003 in men. The effect size was low.
- No impact on quality of life or quality of sleep was demonstrated.
- The most commonly reported adverse events were: dry mouth (13%), headache (3%), hyponatraemia (3%) and dizziness (2%). The most severe adverse effect on desmopressin is hyponatraemia. In clinical studies, it occurred, in most cases, during the first days of treatment or after a dose increase.

Benefit of the medicinal product

- The actual clinical benefit* of NOCDURNA 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 19 July 2017 (CT-15793) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a 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 ACB, which can be substantial, moderate, low or insufficient for reimbursement of the medicinal product for hospital use.