HAUTE AUTORITÉ DE SANTÉ

UROLOGY
New presentation
October 2018

TRANSPARENCY COMMITTEE OPINION SUMMARY

VESICARE oral suspension (solifenacin), cholinergic receptor antagonist

Moderate clinical benefit in the symptomatic treatment of overactive bladder in adults, though no demonstrated clinical advantage over other VESICARE presentations

Insufficient clinical benefit in the treatment of neurogenic bladder in children aged 2 to 18 years

Main points

- VESICARE has been granted an MA in the symptomatic treatment of overactive bladder in adults and neurogenic bladder in children aged 2 to 18 years.
- **In the symptoms of urinary urge incontinence and/or pollakiuria and urinary urgency that can be observed in adults suffering from overactive bladder**, VESICARE 1 mg/ml, oral suspension, is a range extension to VESICARE 5 and 10 mg tablets that are already available for adults.
- **In the treatment of neurogenic bladder in children**, there is no evidence that it is at least as effective as the other anticholinergic medicines available for children over the age of 5 years. Moreover, its effect on the occurrence of episodes of incontinence and on the prevention of complications has not been clearly established. No clinical study data beyond one year of treatment in children and adolescents are available. The data for children under the age of 5 years are very limited.

Therapeutic strategy

- **In the treatment of overactive bladder in adults**
  An anticholinergic medicinal treatment may be proposed as a first line, or after failure of behavioural treatment and/or re-education. It is prescribed after elimination of a urinary tract infection and urinary retention, if there are no contraindications to the use of anticholinergic medicines and if no anticholinesterase treatment is in progress. It is associated with keeping a micturition calendar and with educational measures (distribution of drinks throughout the day, adaptation of the time at which diuretic medicines are taken).
- **In the treatment of neurogenic bladder in children:**
  The aims are to reduce, or even eliminate bladder leakage between micturitions, along with chronic urine retention, to improve the patient's quality of life and to preserve the upper urinary tract.
  Management combines self-catheterisation and pharmacological treatment, or surgery. Self-catheterisation serves to ensure regular, complete and deliberate bladder voiding. Pharmacological treatment combats the cause of incontinence and helps prevent the risks of upper urinary tract complications by reducing endovesical pressure during filling. An anticholinergic treatment may be proposed as a first line to children, combined with intermittent self-catheterisation (ISC). DITROPAN (oxybutynin) is used from the age of 5 years and CERIS from the age of 12 years.
- **Role of the medicinal product in the therapeutic strategy**
  In the treatment of overactive bladder in adults: the VESICARE oral suspension is a range extension to the presentations already available in tablet form.

  In the treatment of neurogenic bladder in children:
  VESICARE 1 mg/ml has no role in the therapeutic strategy due to:
  - the only demonstration of VESICARE efficacy on changes to maximum cystometric capacity (MCC) after 24 weeks of treatment, relative to the initial value,

- the lack of correlation between significant reduction in MCC and a clinical benefit on the severity of urinary incontinence episodes or complications related to this decrease,
- the lack of comparative data allowing its contribution in terms of efficacy and adverse effects relative to another anticholinergic in children over the age of 5 years to be assessed,
- the data from a very small population of children under the age of 5 years.

Clinical data

Overactive bladder in adults:

- No new clinical data for this new presentation.

Neurogenic bladder in children:

- Two 52-week open, controlled versus initial condition studies were conducted: one on young children aged between 6 months and 5 years, the other on children over the age of 5 years. The results show a statistical improvement in maximum cystometric capacity (MCC, primary endpoint) after 24 weeks of treatment relative to the value at week 12 in both studies. These data do not allow the effect of MCC compared to placebo (particularly in children under the age of 5 years), or to another anticholinergic medicinal product with an MA for children aged 5 years and over.
- The known tolerance profile of solifenacin in adults does not appear to change in children, considering that the population sizes and study durations are very limited and that the 12-week titration phase prior to the treatment phase may have excluded children experiencing adverse events under solifenacin.

Benefit of the medicinal product

In the symptomatic treatment of urinary urge incontinence and/or of pollakiuria and urinary urgency that may be observed in patients suffering from overactive bladder:

- The actual clinical benefit* of VESICARE 1 mg/ml, oral suspension, is moderate
- VESICARE 1 mg/ml, oral suspension, does not provide any improvement in actual clinical benefit (IACB V) compared to other VESICARE presentations.
- Approved for non-hospital pharmacy reimbursement or for hospital treatment.

In the treatment of neurogenic bladder in children aged 2 to 18 years:

- The actual clinical benefit* of VESICARE 1 mg/ml, oral suspension, is insufficient to justify public funding cover.
- Not approved for non-hospital pharmacy reimbursement or for hospital treatment.

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This document was drafted on the basis of the Transparency Committee opinion dated 21 November 2018 (CT-17017) available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a medicinal product consists of its benefit particularly on the basis of its clinical performances and the severity of the disease treated. The HAS Transparency Committee assesses the ACB, which may be high, moderate, low, or insufficient for the medicinal product to be covered by public funding.

** The improvement in actual clinical benefit (IACB) consists of the clinical improvement offered by a medicinal product compared to existing treatments. The HAS Transparency Committee assesses the IACB rating from I, major, to IV, minor. An IACB rating of V (equivalent to "no IACB") denotes a "lack of clinical improvement"