



TRANSPARENCY COMMITTEE OPINION 22 APRIL 2020

valsartan
TAREG 3 mg/ml oral solution

New indication

► Key points

Favourable opinion for reimbursement in the treatment of hypertension in children aged 1 to 5 years.

► What therapeutic improvement?

No clinical added value in the therapeutic strategy for hypertension in children aged 1 to 5 years.

► Role in the care pathway?

The treatment of hypertension in children is based on lifestyle and dietary measures as a first-line approach, irrespective of blood pressure level, with or without associated pharmacological treatment. Pharmacological treatment is recommended from the outset in the event of symptomatic hypertension, hypertension associated with damage to a target organ (in particular, the brain, eyes, heart, kidneys), hypertension combined with diabetes (type 1 or 2) or secondary hypertension.

When medicinal treatment is deemed necessary, ACE inhibitors, angiotensin II antagonists, calcium channel blockers, beta-blockers or diuretics may be used as first-line therapy. In the absence of absolute contraindications, the choice of medicinal product must target the underlying pathophysiology of the child's hypertensive disease and the presence of concomitant diseases.

Among the medicinal alternatives, the antihypertensives in oral solution form with an MA are: SECTRAL (acebutolol), NOYADA (captopril) and LASILIX (furosemide). It should be noted that the

proprietary medicinal product HEMANGIOL (propranolol) has received a favourable opinion for a temporary recommendation for use (RTU) in this indication¹.

Role of the medicinal product in the care pathway

TAREG 3 mg/ml oral solution (valsartan) is a first-line treatment in the management of hypertension in children aged 1 to 5 years.

To date, TAREG oral solution (valsartan) is the only medicinal product belonging to the angiotensin II antagonist group to have been awarded an MA in the treatment of hypertension in children less than 6 years of age and for which the delivery form is suitable for the paediatric population.

The Committee highlights the practical value of this oral solution formulation of valsartan for use in very young children.

► Special recommendations

The Committee warns that the multi-dose vial packaging with a dosing device graduated in ml, requiring conversion from mg into ml, is not appropriate. Depending on the dose prescribed, multiple handling operations are required, since the total quantity of solution that can be measured into the syringe is 5 ml. In addition, the packaging includes a dosing cup, which is not intended to be used to measure the valsartan dose but to collect successive quantities of solution drawn using the syringe. All these elements promote the risk of medication errors and overdose. To reduce this risk, the Committee would like a dosing device better suited to the MA dosages, with graduation in mg, to be provided. It would also like only one dosing device to be provided.

¹ The order relating to reimbursement of HEMANGIOL in this RTU has not yet been published in the French Official Journal.

01 COMMITTEE'S CONCLUSIONS

01.1 Clinical benefit

- ▶ Hypertension in children can be life-threatening due to its cerebrovascular or cardiovascular complications.
- ▶ The medicinal product TAREG 3 mg/ml oral solution (valsartan) is a preventive treatment for the complications of hypertension.
- ▶ The efficacy/adverse effects ratio is high in the treatment of hypertension in children less than 6 years of age.
- ▶ There are medicinal alternatives, in particular other antihypertensives in oral solution form: SECTRAL (acebutolol), NOYADA (captopril), LASILIX (furosemide), HEMANGIOL (propranolol under an RTU).
- ▶ This is a first-line treatment in the management of hypertension in children aged 1 to 5 years. TAREG oral solution (valsartan) is the only medicinal product belonging to the angiotensin II antagonist group to have been awarded an MA in the treatment of hypertension in children less than 6 years of age and for which the delivery form is appropriate for the paediatric population.

▶ Public health impact

Considering:

- the risk of morbidity and mortality associated with this risk factor,
- the low prevalence of hypertension in children less than 6 years of age,
- the partially met medical need,
- the absence of long-term data enabling demonstration of an impact of valsartan on the morbidity and mortality of treated children,
- the absence of an additional impact on the organisation of care, given that this medicinal product is already available in oral solution form in the treatment of hypertension in children aged 6 years or more,
- the absence of a demonstrated impact in terms of improvement of quality of life,
- the partial response to the identified medical need,

TAREG 3 mg/ml oral solution (valsartan) is unlikely to have an additional impact on public health in the current management of hypertension in children less than 6 years of age.

Considering all these elements, the Committee deems that the clinical benefit of TAREG 3 mg/ml oral solution is substantial in the treatment of hypertension in children aged 1 to 5 years.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication(s) and dosages.

01.2 Clinical Added Value

Considering:

- demonstration of the short-term efficacy of valsartan oral solution in terms of reduction in systolic blood pressure (interim endpoint) in children less than 6 years of age in 2 out of 3 studies, one having demonstrated a reduction in SBP versus placebo and the other a dose-dependent reduction in SBP,
- the absence of comparison of valsartan with the other antihypertensive products available in this population, whereas these comparisons could have been performed,

the Committee considers that TAREG 3 mg/ml oral solution (valsartan) provides no clinical added value (CAV V) in the current care pathway for the treatment of hypertension in children aged 1 to 5 years.

The Committee highlights the practical value of this oral solution formulation of valsartan for use in very young children.