BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

TRAVATAN (travoprost), glaucoma eye drops

No clinical benefit demonstrated in paediatric patients, by comparison with its comparators, in the reduction of elevated intraocular pressure

Main points

- TRAVATAN now has Marketing Authorisation in the reduction of elevated intraocular pressure (IOP), from 2 months of age, in paediatric patients with intraocular hypertension or glaucoma.
- A study has demonstrated its non-inferiority relative to timolol after 12 weeks of treatment on the reduction of IOP in children.
- No long-term safety data are available.
- TRAVATAN contains excipients that may cause a skin reaction.

Pre-existing indications

- TRAVATAN already has Marketing Authorisation in the reduction of elevated intraocular pressure in adult patients with ocular hypertension or open-angle glaucoma.

Therapeutic use

- In the majority of congenital glaucoma cases, and due to the urgency of care, the first-line treatment is surgical. Nevertheless, topical treatment with glaucoma eye drops can be useful short-term, while awaiting surgery, or as an additional treatment with surgery whose result is insufficient or when surgery is not possible.
- In other forms of glaucoma, the treatment objective is first of all to treat the cause of the ocular hypertension and there are many situations where a medical treatment is prescribed first line because the seriousness of the initial clinical presentation does not justify surgery right away.
- Regardless of the aetiology of the elevated IOP, topical treatment with eye drops is a temporary treatment adjunct to surgery, but treatments can be prolonged in some special forms of secondary glaucoma (cortisone glaucoma).
- Role of the medicinal product in the therapeutic strategy
  Travoprost, like other glaucoma eye drops, can be useful short-term, while awaiting surgery, or as an additional treatment with surgery whose result is insufficient.
  In other, less aggressive forms of glaucoma in paediatric patients, like other eye drops, travoprost is a long-term first-line treatment.
  In the case of active ocular inflammation or aphakia, prostaglandin analogues are not a treatment of choice to reduce intraocular hypertension due to the increased risk of macular oedema.

* This summary does not cover this indication.
Clinical data

- A non-inferiority study compared travoprost to timolol after 3 months of treatment in 152 patients under 18 years of age. The patients were randomised to receive either travoprost 0.004% once daily or timolol 0.5% (or timolol 0.25% for patients under 3 years of age) twice daily. Timolol does not have specific paediatric Marketing Authorisation even though efficacy data are available.
- Patient characteristics were comparable between the groups, with a mean age of 9.6 years and mean baseline IOP comprised between 24.2 and 24.7 mmHg.
- After 12 weeks of treatment and relative to baseline, the mean IOP reduction (primary endpoint) was 6.4 mmHg in the travoprost group and 5.8 mmHg in the timolol group, or a difference of 0.5 mmHg (95% CI [-2.1; 1.0]), demonstrating the non-inferiority of travoprost relative to timolol with a predefined margin of 3 mmHg, in the per-protocol population (n=144). TRAVATAN did not show any superiority over timolol in terms of the reduction of intraocular pressure.
- The safety profile of TRAVATAN in paediatric patients was comparable to that of adults. Ocular hyperaemia was the most common adverse effect. Other ocular adverse effects reported, related to the treatment, were eye discomfort, photophobia, lacrimation, ocular dryness, irritation of the surface of the cornea. There are no long-term safety data.

Benefit of the medicinal product

- The actual benefit* of TRAVATAN is substantial.
- TRAVATAN provides no clinical added value** (CAV V) in the treatment strategy for managing paediatric patients with elevated intraocular pressure with paediatric glaucoma that includes surgery and glaucoma eye drops (latanoprost, timolol, dorzolamide and brinzolamide).
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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* 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.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".