HAUTE AUTORITÉ DE SANTÉ

OPHTHALMOLOGY
Update
February 2019

TRANSPARENCY COMMITTEE OPINION SUMMARY

GANFORT (bimatoprost, timolol), antiglaucoma

High clinical benefit in the treatment of open angle glaucoma or ocular hypertension when the response to topical beta-blockers or prostaglandin analogues is insufficient, but no demonstrated clinical advantage in the therapeutic strategy.

Main points

- GANFORT has been granted a marketing authorisation for the treatment of patients suffering with open angle glaucoma or ocular hypertension and whose response to topical beta-blockers or prostaglandin analogues is insufficient.
- The new clinical data failed to demonstrate the superiority of GANFORT over other eye drops combining a prostaglandin analogue with timolol.

Therapeutic strategy

- Therapy is initially medical, though surgery is preferred when the glaucoma is advanced, or when the subject is young. Laser trabeculoplasty may be used after failure of medicinal treatment and before considering surgery. Many medicinal products are available, in local or systemic form, acting according to various mechanisms:
  - reduction of aqueous humour secretion: beta-blockers, alpha-2 adrenergic antagonists, carbonic anhydrase inhibitors
  - increase aqueous humour elimination: adrenaline and adrenaline, myotic and parasympathomimetic compounds, prostaglandin analogues.

  Beta-blocker and prostaglandin analogue eye drops are the first-line treatments. Several hypotonic eye drops can be combined, though as a general rule, a tritherapy should not be exceeded.
  In the context of bitherapy, prostaglandin analogues and beta-blockers can be combined, if one or the other has been found to be ineffective in first-line monotherapy.
  The other hypotonic eye drops are prescribed:
  - either as first-line monotherapy, in the event of contraindication to beta-blockers and prostaglandin analogues;
  - or as second-line monotherapy, or combined with beta-blockers or prostaglandin analogues, when the efficacy of these latter is insufficient.

  In some cases that cannot be curbed by topical treatment, this latter may be combined with acetazolamide, a systemic carbonic anhydrase inhibitor.
- In cases of chronic administration, the preservatives found in the eye drops may induce adverse conjunctival inflammatory effects and eye surface toxicity. Consequently, preservative-free eye drops should be preferred.
- **Role of the medicinal product in the therapeutic strategy**

  GANFORT is a second-line treatment for patients suffering from open angle glaucoma or ocular hypertension, to be reserved for cases of failure of a beta-blocker or prostaglandin analogue eye drop monotherapy.

Clinical data

- Two new studies compared the bimatoprost/timolol combination to two other fixed prostaglandin analogue/timolol combinations.
  In one crossover, single-centre, randomised single-blind (hidden investigator) study, no significant difference between the bimatoprost/timolol and travoprost/timolol combinations was observed in terms of mean diurnal intraocular pressure (IOP) variation in adults with open angle glaucoma or ocular hypertension, already treated with a non-fixed combination of 0.0005% latanoprost and 0.5% timolol for 3 months, with an IOP of 21 mmHg or less.
  One single-centre, randomised, single-blind (hidden investigator), parallel group study compared the travoprost/timolol combination to two other combinations (bimatoprost/timolol and latanoprost/timolol) in adults with open angle glaucoma or ocular hypertension with an IOP ≥21 mmHg upon inclusion and previously treated with at least two hypotensive medicinal products. These results cannot be considered due to significant methodological biases.
- The safety profile of GANFORT has not changed since the previous assessment. The most frequent adverse effect is generally mild to moderate conjunctival congestion, not considered inflammatory.

Benefit of the medicinal product

- The actual clinical benefit* of GANFORT is high
- GANFORT does not provide any clinical added value** (CAV V) in the management of patients suffering with open angle glaucoma or ocular hypertension and whose response to topical beta-blockers or prostaglandin analogues is insufficient.
- Approved for continuing 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 20 February 2019 (CT-15109) 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 may be high, moderate, low, or insufficient for the medicinal product to be covered by public funding.

** The clinical added value (CAV) corresponds to the clinical improvement offered by a medicinal product compared to existing treatments. The HAS Transparency Committee assesses the CAV level from I, major, to IV, minor. A level V CAV (equivalent to "no clinical added value") denotes a "lack of clinical improvement".