

SUMMARY

bimatoprost/timolol

BITIFRIN 0.3 mg/5 mg/mL

eye drops, solution

Inclusion on list: First listing

Hybrid

Adopted by the Transparency Committee on 20 November 2024

Summary of opinion

Favourable opinion for reimbursement in the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

No clinical added value compared to the reference medicinal product, GANFORT 0.3 mg/5 mg/mL eye drops, solution in single-dose containers.

This document and its bibliographic reference are available to download at www.has-sante.fr 

This opinion is published subject to intellectual property rights

Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

© Haute Autorité de santé – November 2024

Transparency Committee's conclusions

Clinical Benefit

- Open-angle glaucoma and ocular hypertension are severe conditions that can cause blindness.
- This proprietary medicinal product is a preventive treatment for complications of the condition.
- The efficacy/adverse effects ratio is high.
- This is a second-line treatment in patients with open-angle glaucoma or ocular hypertension to be reserved for cases of inadequate response to beta-blocker eye drops or prostaglandin analogues as monotherapy.

→ Public health benefit

BITIFRIN (bimatoprost/timolol) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of BITIFRIN (bimatoprost/timolol) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

Clinical Added Value

This medicinal product is a hybrid that does not provide any clinical added value (CAV V) compared to the reference medicinal product, GANFORT 0.3 mg/5 mg per mL (bimatoprost/timolol) eye drops, solution.