

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

dorzolamide, timolol

OLATALIN 20 mg/mL + 5 mg/mL

eye drops, solution

Inclusion on list: First listing

Hybrid

Adopted by the Transparency Committee on 12 February 2025

Summary of opinion

Favourable opinion for reimbursement in the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or pseudoexfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.

No clinical added value of the new forms compared to the reference medicinal product, COSOPT 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution in single-dose containers, and the other preservative-free eye drop solutions containing dorzolamide 20 mg/mL and timolol 5 mg/mL (COSTEC, COSIDIME and DUALKOPT).

Transparency Committee's Conclusions

Clinical Benefit

- ➔ Chronic open-angle glaucoma and pseudoexfoliative glaucoma are severe conditions that can cause blindness.
- ➔ OLATALIN 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution is a preventive treatment for complications of the condition.
- ➔ The efficacy/adverse effects ratio is high.

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- It is a second-line treatment in view of the available alternatives in patients with chronic open-angle glaucoma or pseudoexfoliative glaucoma who have not responded to treatment with beta-blocker eye drop monotherapy.

- **Public health benefit**

OLATALIN 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution is unlikely to have an additional impact on public health compared to the reference medicinal product, COSOPT 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution in single-dose containers, and the other preservative-free eye drop solutions containing dorzolamide 20 mg/mL and timolol 5 mg/mL (COSTEC, COSIDIME and DUALKOPT).

The Committee considers that the clinical benefit of OLATALIN 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution 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.

- **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

The proprietary medicinal product OLATALIN 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution is a hybrid that does not provide any clinical added value (CAV V) compared to the reference medicinal product, COSOPT 20 mg/mL + 5 mg/mL (dorzolamide, timolol) eye drops, solution in single-dose containers, and the other preservative-free eye drop solutions containing dorzolamide 20 mg/mL and timolol 5 mg/mL (COSTEC, COSIDIME and DUALKOPT).