

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

dorzolamide

OFRIRI 20 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 intra-ocular pressure in subjects with ocular hypertension, open-angle glaucoma or pseudoexfoliative glaucoma.

No clinical added value compared to the reference medicinal product already available (TRUSOPT 20 mg/mL (dorzolamide) eye drops, solution).

Transparency Committee's Conclusions

Clinical Benefit

- Ocular hypertension, open-angle glaucoma and pseudoexfoliative glaucoma are severe conditions that can cause blindness.
- OFRIRI 20 mg/mL (dorzolamide) eye drops, solution is a preventive treatment for complications of the condition.
- The efficacy/adverse effects ratio is high.
- This is a second-line treatment in view of the available alternatives, used as monotherapy in adults unresponsive to beta-blockers or in whom beta-blockers are contraindicated, or as adjunctive therapy to beta-blockers.

→ Public health benefit

OFRIRI 20 mg/mL (dorzolamide) eye drops, solution is unlikely to have an additional impact on public health compared to the reference medicinal product, TRUSOPT 20 mg/mL (dorzolamide) eye drops, solution.

The Committee considers that the clinical benefit of OFRIRI 20 mg/mL (dorzolamide) eye drops, solution is substantial in the MA indications.

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 OFRIRI 20 mg/mL (dorzolamide) eye drops, solution is a hybrid that does not provide any clinical added value (CAV V) compared to the reference medicinal product, TRUSOPT 20 mg/mL (dorzolamide) eye drops, solution.