

Dorzolamide / Timolol – new preservative-free formulation

Product:

DORZOLAMIDE / TIMOLOL
(Cosopt® Preservative Free) 2%/0.5%
ophthalmic solution (new formulation)

Class of drugs:

Carbonic anhydrase inhibitor /
beta-blocker combination

Indication:

Treatment of ocular hypertension and
open-angle glaucoma

Manufacturer:

Merck Frosst Canada Ltd.

CED Recommendation

The CED recommended that preservative-free dorzolamide/timolol (Cosopt Preservative Free) not be funded on the basis that it has not been shown to improve tolerability or provide any other clinical advantage; therefore, the significant price premium could not be justified.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund preservative-free dorzolamide/timolol (Cosopt Preservative Free).

Status

Funding not available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Cosopt is an eye drop combining two drug ingredients, dorzolamide and timolol, used to treat increased intraocular pressure (pressure in the eye) associated with ocular hypertension or glaucoma.
- ◆ Cosopt (with benzalkonium chloride as a preservative) is already available in a multi-use bottle and is listed on the Ontario Drug Benefit Formulary as a Limited Use benefit. Cosopt Preservative Free is a new formulation that does not contain benzalkonium and comes in individual, single-use packages.
- ◆ The Committee reviewed a study comparing the efficacy and safety of the new preservative-free dorzolamide/timolol (Cosopt Preservative Free) with the original preservative-containing formulation. Both preparations were found to be equally effective in lowering intraocular pressure, and there were no significant differences in tolerability between the two formulations.
- ◆ The Committee acknowledged that some patients may experience minor irritation with the use of preservative-containing eye drops but questioned the incidence of true allergic reactions to benzalkonium chloride that can only be managed with the use of a preservative-free preparation. It was noted that studies demonstrating intolerance to benzalkonium chloride were conducted by administering high concentrations of the preservative directly into the eyes of animals.
- ◆ Preservative-free dorzolamide/ timolol (Cosopt Preservative Free) costs \$56.85 per 60-unit package (one month of treatment). This is more than three times the cost of the preservative-containing formulation.
- ◆ **Overall, the Committee noted that evidence of improved tolerability with preservative-free dorzolamide/ timolol (Cosopt Preservative Free) is lacking. Moreover, the incidence of true allergic reaction to benzalkonium is unknown. For these reasons, the Committee indicated that the significant price premium for the preservative-free preparation could not be justified.**

Background:

Cosopt is an eye drop combining two drug ingredients, dorzolamide and timolol, used to treat increased intraocular pressure (pressure in the eye) associated with ocular hypertension or glaucoma. Increased intraocular pressure over time leads to progressive damage to the optic nerve and can result in vision loss and blindness. These medications work by reducing the production of fluid in the eye, thereby lowering the pressure in the eye.

Cosopt (with preservative) is listed on the Ontario Drug Benefit Formulary as a Limited Use benefit according to the following criteria:

As second-line therapy for patients who do not have an adequate intraocular pressure lowering response to single-drug therapy with ophthalmic beta-blocking agents.

OR

For use as initial therapy in an urgent situation (e.g., patients with a high baseline intraocular pressure) where single-drug therapy is unlikely to be effective.

continued...

Detailed Discussion:

No additional details. The full CED discussion is as outlined in the Highlights of Recommendation section.

CEDAC Recommendation:

[\(<http://www.cadth.ca/index.php/en/cdr/recommendations>\)](http://www.cadth.ca/index.php/en/cdr/recommendations)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review dorzolamide/timolol (Cosopt Preservative Free).



Ministry of
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