



Therapeutic Class ReviewSM

Timolol maleate (Istalol[®])

[Ista]

May 2005

New Product for Review

timolol maleate (Istalol) - Ista

Dossier Provided by Manufacturer: Yes

Available Therapeutic Alternative(s)

Preferred/Formulary	Non-Preferred/Non-Formulary
timolol maleate 0.25%, 0.5% gel, solutions	
timolol hemihydrate (Betimol [®]) 0.25%, 0.5% solutions	
levobunolol HCl (generic), 0.25%, 0.5% solutions	
betaxolol HCl (generic), 0.25%, 0.5% solutions	
metipranolol HCl (generic), 0.25%, 0.5% solutions	
carteolol HCl (generic), 1% solution	

Executive Summary

- There are many ophthalmic β -blockers on the formulary to lower intraocular pressure (IOP) in patients with primary open angle glaucoma (POAG).
- There is no evidence that timolol maleate as a once daily formulation is superior in lowering IOP than twice daily preparations of timolol maleate.
- Once daily ophthalmic timolol maleate formulation has potassium sorbate and 50% less benzalkonium chloride than twice-daily timolol maleate preparation.
 - There is no evidence that the addition of potassium sorbate increases ocular penetration of timolol or provides additional clinical benefit.
 - The lower benzalkonium chloride has not shown to be less allergenic.
- Once daily formulation of timolol maleate is associated with significantly higher incidence of ocular adverse effects, such as stinging or burning sensation, eye infections, visual field defects and cataracts.

Conclusion

Timolol maleate (Istalol) is non-formulary/non-preferred because this product offers no additional medical value over its comparators in lowering IOP in individuals with POAG.

Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	AWP Cost*	Potential Off-Label Use(s)
Timolol maleate (Istalol®). 0.5% timolol ophthalmic solution with 0.47% potassium sorbate and 0.005% benzalkonium chloride	06/04/2004	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$44 for 5 mL	None
Timolol maleate (generic) 0.25%, 0.5% ophthalmic solutions	11/04/1993	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$4.50 10 mL** (0.25%) \$5.40 10 mL** (0.5%)	None
Timolol maleate (Timoptic-XE®). 0.25%, 0.5% ophthalmic gel forming solution	03/18/1998	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$29 for 5 mL	None
Timolol hemihydrate (generic) 0.25%, 0.5% ophthalmic solution	03/31/1995	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$19 for 5 mL	None
Levobunolol HCl (generic) 0.25%, 0.5% ophthalmic solutions	06/28/1989	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$7 5 mL** \$8 10 mL**	None
Betaxolol HCl (generic) 0.25%, 0.5% ophthalmic solutions	08/30/1985	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$26 5 mL	None
Carteolol HCl (generic) 1% ophthalmic solution	05/23/1990	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$20 10 mL**	None
Metipranolol HCl (generic) 0.25%, 0.5% ophthalmic solutions	12/29/1989	Treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	Ophthalmic	\$16 5 mL	None

*AWP (average wholesale price) based on First Data Bank as of December 30, 2004 for one month therapy

**Based on Maximum Allowable Cost (MAC) as of September 2004 for one month supply

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