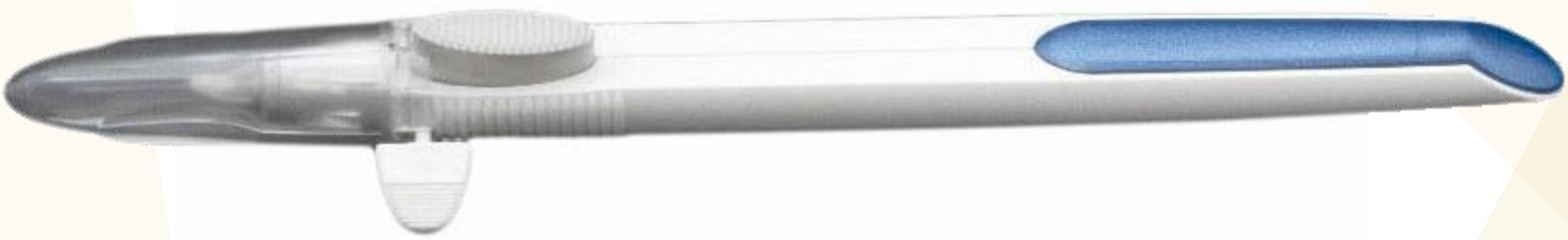
# **Durysta** (bimatoprost implant)



**NEW PRODUCT SLIDESHOW**

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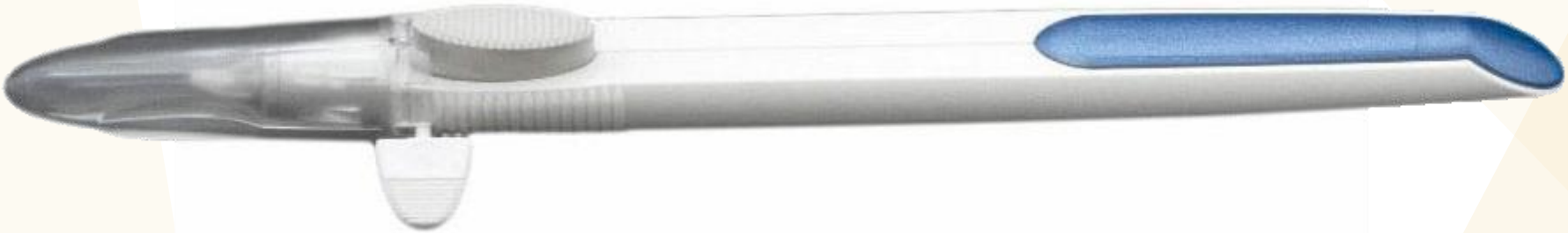
# Introduction

- **Brand name:** Durysta
- **Generic name:** Bimatoprost
- **Pharmacologic class:** Prostaglandin analogue
- **Strength and Formulation:** 10mcg per implant; for intracameral administration
- **Manufacturer:** Allergan
- **How supplied:** Implant—1 (w. applicator)
- **Legal Classification:** Rx

# Durysta



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# Indication

- Reduction of intraocular pressure in patients with **open angle glaucoma** or **ocular hypertension**.

# Dosage and Administration

- See full labeling.
- Perform intracameral injection procedure under magnification as directed.
- Durysta is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant.
- Limited to a single implant per eye.
- Should not be readministered to an eye previously treated with Durysta.

# Considerations for Special Populations

- **Pregnancy:** No adequate studies to inform risk.
- **Nursing mothers:** No information regarding presence in human milk; consider benefits of breastfeeding along with mother's need for Durysta and any potential adverse effects.
- **Pediatric**: Not established.
- **Geriatrics**: No overall differences in safety or effectiveness.

# Contraindications

- Ocular or periocular infections.
- Corneal endothelial cell dystrophy (eg, Fuchs dystrophy).
- Prior corneal transplantation or endothelial cell transplants (eg, Descemet stripping automated endothelial keratoplasty).
- Absent or ruptured posterior lens capsule.

# Warnings and Precautions

- Increased risk of corneal endothelial cell loss.
- Patients with limited corneal endothelial cell reserve; use caution.
- Use with caution in patients with narrow iridocorneal angles (Shaffer grade <3) or anatomical obstruction (eg, scarring) that may prohibit settling in the inferior angle.
- Use with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

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# Warnings and Precautions

- Active intraocular inflammation (eg, uveitis); inflammation may be exacerbated.
- Increased iris pigmentation
  - Pigmentation is likely permanent.
  - While treatment can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.
- Monitor for endophthalmitis.

# Adverse Reactions

- **Most common ocular adverse reaction (27%)**: conjunctival hyperemia
- **Other adverse reactions (5-10%)**: foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, iritis, headache

# Mechanism of Action

- **Bimatoprost** is a synthetic structural analogue of prostaglandin with ocular hypotensive activity.
- It is believed to lower intraocular pressure (IOP) in humans by increasing outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral routes (unconventional).

# Clinical Trials

- Efficacy was evaluated in 2 multicenter, randomized, parallel-group, controlled 20-month (including 8 month extended follow-up) studies in patients with open-angle glaucoma or ocular hypertension.
- Patients were randomized to receive either Durysta or twice daily topical timolol 0.5% drops.
- Durysta demonstrated an IOP reduction of approximately 5-8mmHg in patients with a mean baseline IOP of 24.5mmHg

# New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/durysta/