

## Durysta<sup>™</sup> (bimatoprost implant) – New drug approval

- On March 5, 2020, <u>Allergan announced</u> the <u>FDA approval</u> of <u>Durysta (bimatoprost implant)</u>, for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).
- Durysta, a prostaglandin analog, is the first intracameral, biodegradable sustained-release implant for patients with OAG or OHT.
- Bimatoprost is also available generically as an <u>ophthalmic solution</u> for the same indication as Durysta.
- The efficacy of Durysta was established in two randomized, controlled 20-month studies of Durysta compared to twice daily topical <u>timolol 0.5% drops</u>, in patients with OAG or OHT.
  - Durysta demonstrated an IOP reduction of approximately 5 to 8 mmHg in patients with a mean baseline IOP of 24.5 mmHg.
- Durysta is contraindicated in patients with:
  - Active or suspected ocular or periocular infections
  - Corneal endothelial cell dystrophy (eg, Fuchs' Dystrophy)
  - Prior corneal transplantation, or endothelial cell transplants (eg, Descemet's Stripping Automated Endothelial Keratoplasty)
  - Posterior lens capsule that is absent or ruptured, due to the risk of implant migration into the posterior segment
  - Hypersensitivity to bimatoprost or to any other components of the product.
- Warnings and precautions for Durysta include corneal adverse reactions, iridocorneal angle, macular edema, intraocular inflammation, pigmentation, and endophthalmitis.
- The most common ocular adverse reaction (in 27%) with Durysta use was conjunctival hyperemia. Other common adverse reactions (5% to 10%) with Durysta use were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, increased IOP, corneal endothelial cell loss, blurred vision, iritis, and headache.
- Durysta is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant. Durysta should not be readministered to an eye that received a prior Durysta.
  - The intracameral administration should be carried out under standard aseptic conditions.
  - Refer to the Durysta drug label for additional administration recommendations.
- Allergan's launch plans for Durysta are pending. Durysta will be available as an intracameral implant containing 10 mcg of bimatoprost in a drug delivery system.



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