DURYSTA™ (bimatoprost implant) 10 mcg

Fact Sheet

How DURYSTA™ Works

DURYSTA™ is the first FDA-approved intracameral, biodegradable sustained-release implant indicated to reduce intraocular pressure in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

DURYSTA™ is preloaded into a single-use applicator to facilitate the administration of the biodegradable implant directly into the anterior chamber of the eye.

DURYSTA™ is an opthalmic drug delivery system (DDS) for a single intracameral adminstration, and should only be administered once per eye.

DURYSTA™ will be administered by an eye care professional.

The implant provides drug for a sustained duration of IOP-lowering effect over a 12-week primary efficacy period.

DURYSTA™ was designed to offer patients an alternative IOP-lowering option to topical medications (eye drops).

DURYSTA™ is preservative free.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DURYSTA™ is contraindicated in patients with: active or suspected ocular or periocular infections; corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy); prior corneal transplantation or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)); absent or ruptured posterior lens capsule, due to the risk of implant migration into the posterior segment; hypersensitivity to bimatoprost or to any other components of the product.

Important Safety Information continues on the next page.

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Clinical Studies

ARTEMIS includes two multicenter, randomized, parallel-group, controlled 20-month (including 8-month extended follow-up) studies evaluating a total of

1,122 patients

(n=594 in study 1, n=528 in study 2)

on the efficacy and safety of

DURYSTA™ (bimatoprost implant)

versus twice-daily topical timolol 0.5% drops in patients with OAG or OHT.

DURYSTA™ has been approved by the United States Food and Drug Administration for the reduction of IOP in patients with OAG or OHT.

DURYSTA™ lowered IOP in patients with glaucoma or ocular hypertension by up to 33% (5-8 mm Hg) from a mean baseline IOP of 24.5 mmHg.

The safety of DURYSTA™ was demonstrated in two Phase 3 clinical trials.

The most common ocular adverse reaction observed in two randomized, active-controlled clinical trials with DURYSTA in patients with OAG or OHT was conjunctival hyperemia, which was reported in 27% of patients. Other common ocular adverse reactions reported in 5-10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, and iritis.

The studies are ongoing.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

The presence of DURYSTA™ implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Administration of DURYSTA™ should be limited to a single implant per eye without retreatment. Caution should be used when prescribing DURYSTA™ in patients with limited corneal endothelial cell reserve.

DURYSTA™ should be used with caution in patients with narrow iridocorneal angles (Shaffer grade < 3) or anatomical obstruction (e.g., scarring) that may prohibit settling in the inferior angle.

Important Safety Information continues on the next page.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Macular edema, including cystoid macular edema, has been reported during treatment with ophthalmic bimatoprost, including DURYSTA™ intracameral implant. DURYSTA™ should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Prostaglandin analogs, including DURYSTA™, have been reported to cause intraocular inflammation. DURYSTA™ should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Ophthalmic bimatoprost, including DURYSTA™ intracameral implant, has been reported to cause changes to pigmented tissues, such as increased pigmentation of the iris. Pigmentation of the iris is likely to be permanent. Patients who receive treatment should be informed of the possibility of increased pigmentation. While treatment with DURYSTA™ can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Intraocular surgical procedures and injections have been associated with endophthalmitis. Proper aseptic technique must always be used with administering DURYSTA™, and patients should be monitored following the administration.

ADVERSE REACTIONS

In controlled studies, the most common ocular adverse reaction reported by 27% of patients was conjunctival hyperemia. Other common adverse reactions reported in 5%-10% of patients were foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, intraocular pressure increased, corneal endothelial cell loss, vision blurred, iritis, and headache.

Please see link to full prescribing information.

For more information about DURYSTA™, visit **www.DURYSTAhcp.com**.

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