LATISSE® Professional Important Safety Information

(Note: All text in black is required, text highlighted is optional, text in green needs to be included when the piece meets the stated requirements)

LATISSE® (bimatoprost ophthalmic solution) 0.03% Important Information

Indication

LATISSE® (bimatoprost ophthalmic solution) 0.03% is indicated to treat hypotrichosis of the eyelashes by increasing their growth, including length, thickness, and darkness.

Important Safety Information

Contraindications: LATISSE® is contraindicated in patients with hypersensitivity to bimatoprost or to any of the ingredients.

Warnings and Precautions: In patients using **LUMIGAN®** (bimatoprost ophthalmic solution) or other prostaglandin analogs for the treatment of elevated intraocular pressure (IOP), the concomitant use of **LATISSE®** may interfere with the desired reduction in IOP. Patients using prostaglandin analogs including **LUMIGAN®** for IOP reduction should only use **LATISSE®** after consulting with their physician and should be monitored for changes to their intraocular pressure.

Increased iris pigmentation has occurred when bimatoprost solution was administered. Patients should be advised about the potential for increased brown iris pigmentation, which is likely to be permanent.

Bimatoprost has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long as bimatoprost is administered, but has been reported to be reversible upon discontinuation of bimatoprost in most patients.

There is the potential for hair growth to occur in areas where **LATISSE®** solution comes in repeated contact with skin surfaces. Apply **LATISSE®** only to the skin of the upper eyelid margin at the base of the eyelashes.

LATISSE® solution should be used with caution in patients with active intraocular inflammation (eg, uveitis) because the inflammation may be exacerbated. **LATISSE®** 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.

[*If the piece discusses directions for use, include this text from Warnings and Precautions at this point in the Fair Balance.*] It is important to use **LATISSE®** solution as instructed, by placing one drop on the single-use-per-eye applicator. The bottle tip should not be allowed to contact any other surface since it could become contaminated. **LATISSE®** contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

Adverse Reactions: The most frequently reported adverse reactions were eye pruritus, conjunctival hyperemia, skin hyperpigmentation, ocular irritation, dry eye symptoms, and periorbital erythema. These reactions occurred in less than 4% of patients.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of **LATISSE®**: dry skin of the eyelid and/or periocular area, eye swelling, eyelid edema, hypersensitivity (local allergic reactions), lacrimation increased, madarosis and trichorrhexis (temporary loss of a few eyelashes to loss of sections of eyelashes, and temporary eyelash breakage, respectively), periorbital and lid changes associated with a deepening of the eyelid sulcus, rash (including macular and erythematous), skin discoloration (periorbital), and vision blurred.

For more information on LATISSE®, please see the accompanying full Prescribing Information.

Please see LATISSE® full Prescribing Information. <link to PI asset>

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