American Academy of Ophthalmology

Position Statement on LATISSE

KEY MESSAGE: If you have an eye condition, such as glaucoma, macular edema or eye inflammation, consult with your ophthalmologist, Eye MD, before using LATISSE[™]. Closely follow the instructions for use of the drug. If you have any concerns, the easiest thing to do is to see your ophthalmologist who can evaluate you to make sure you are a good candidate for LATISSE as well as prescribe it.

DETAILS AND BACKGROUND

The new prescription drug, LATISSE[™] (bimatoprost ophthalmic solution) 0.03% by Allergan, was recently approved by the FDA as safe and effective to help lengthen, thicken and darken eyelashes. It has the same active ingredient, a prostaglandin analog, as a glaucoma drug, Lumigan[®] (bimatoprost ophthalmic solution) 0.03%, also made by Allergan. It was discovered that one of the side effects of Lumigan is increased eyelash length, darkening and thickening. Other side effects include eye redness, irritation and darkening of the skin of the eyelids, all of which are reversible upon cessation of drug. Darkening of the iris has also been reported and this side effect is not reversible.

The FDA studies show that the most common adverse events (about 3-4% incidence) are itchiness of eyes, redness of eyes and increased pigmentation. As per the prescribing information for LATISSE[™], the American Academy of Ophthalmology advises the following advice and precautions:

- See a doctor before using LATISSE.
- If you are currently taking a prostaglandin analog, concurrent use of LATISSE[™] may interefere with the desired IOP reducing effect. Therefore, you should be closely monitored by your ophthalmologist while using LATISSE[™].
- If you have intraocular inflammation (uveitis), consult your ophthalmologist before using LATISSE[™]. It could make the inflammation worse.
- If you have risk factors for macular edema, consult your ophthalmologist before using LATISSE[™]. Lumigan[®] has been associated with formation of macular edema.
- While on LATISSE[™], if you develop a new ocular condition, have a sudden decrease in visual acuity, have ocular surgery or develop any ocular reactions, immediately seek medical advice concerning the continued use of LATISSE[™] Only an Eye MD, an ophthalmologist, has the medical training in eye care to assess your particular reactions and conditions.
- LATISSE ™is not approved for people under the age of 18. It is not recommended for pregnant or lactating women.
- LATISSE ™is a prescription drug and should not be used by anyone else other than the person it was prescribed to.
- Be sure to carefully follow the package insert instructions.
- Do not reuse the single-use applicator or contaminate the bottle by allowing the bottle tip to come into contact with any other surface. Doing so may lead to serious eye infections.
- Take your contact lenses out prior to application, and reinsert 15 minutes later.

- Please note that upon discontinuation of LATISSE[™], lash length, thickening and darkening will revert back to pre-medication appearance.
- Darkening of the iris, which is likely permanent, may occur with the use of LATISSE.
- Tell your Eye MD if you are using LATISSE.

The safety data supporting the FDA's approval of LATISSE[™] derived from a clinical study of 278 people who underwent four months of treatment. In addition, Allergan has applied for study in pediatric patients, and is committed to perform a postmarketing study of African-American subjects.