

Bimatoprost Proves to Be Well Tolerated

BY MARY ELLEN SCHNEIDER

Just as patients are beginning to come into the office seeking eyelashes as long and thick as those belonging to Brooke Shields, Dr. Christopher B. Zachary gave his run-down on the safety and efficacy of bimatoprost 0.03%.

The bottom line appears to be that the product has a clinically meaningful benefit and is well tolerated in healthy

adults, Dr. Zachary said at a cosmetic dermatology seminar sponsored by Skin Disease Education Foundation (SDEF).

“Appropriate studies have been performed to demonstrate the efficacy and safety of this product,” he said in an interview. “But as with any new cosmetic procedure, patients need to be aware of the potential for side effects.”

Eyelash growth using bimatoprost was first characterized in two controlled

phase III trials in glaucoma. The discovery of a secondary application for bimatoprost is not a surprise, said Dr. Zachary, chair of the department of dermatology at the University of California, Irvine. “Many products when developed and utilized extensively for one indication will inevitably be associated with effects in other systems,” said Dr. Zachary, who serves on various academic advisory boards for Allergan Inc.

Since the benefit was first observed in glaucoma patients, researchers performed an open-label trial showing the efficacy of bimatoprost when directly applied to the eyelid margin.

The open label, proof-of-concept study included 28 women who applied the product daily over the course of 12 weeks. The study demonstrated the effectiveness of the product, with all women who responded to questions about efficacy reporting at least some improvement in their eyelashes. None of the patients discontinued treatment as a result of adverse events, and only minor, transient adverse events were reported. Additionally, changes in intraocular pres-

Promiseb[™] Topical Cream

For Topical Dermatological Use Only

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Product Description:

Promiseb[™] Topical Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.

Indications for Use:

Under the supervision of a healthcare professional, Promiseb Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Promiseb Topical Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Directions for Use:

Apply Promiseb Topical Cream to the affected skin areas 2 to 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover Promiseb Topical Cream with a dressing of choice.

Ingredients:

Promiseb Topical Cream is comprised of Purified Water, Isohexadecane, Butyrospermum parkii, Pentylene glycol, Ethylhexyl palmitate, Cera alba, PEG-30 Dipolyhydroxystearate, Bisabolol, Polyglyceryl-6 polyricinoleate, Tocopheryl acetate, Hydrogenated castor oil, Acifructol complex, Butylene glycol, Magnesium sulfate, Piroctone olamine, Allantoin, Magnesium stearate, Disodium EDTA, Vitis vinifera, Ascorbyl tetraisopalmitate, Glycyrrhetic acid, Propyl gallate, and Telmesteine.

Caution:

The use of Promiseb Topical Cream is contraindicated in any patient with a known history of hypersensitivity to any of the ingredients. Promiseb Topical Cream does not contain milk, wheat, peanut or animal derivatives. Promiseb Topical Cream does contain shea butter (Butyrospermum parkii), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

How Supplied:

30 g tube, NDC 67857-803-30

To Open: Puncture seal with pointed end of cap.

Important: The opening of this product is covered by a metal seal. Do not use if seal has been punctured or is not visible.

Store at controlled room temperature 68° to 77°F (20° to 25°C), excursions permitted between 59° and 86°F (15° and 30°C).

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References:

1. Data on file. A randomized pilot study to compare the safety and efficacy of Promiseb Topical Cream and desonide cream 0.05% in the treatment of mild to moderate seborrheic dermatitis of the face. Promius Pharma, LLC: Bridgewater, NJ; 2008. PSC0801.
2. Data on file. An open-label, single-center, pilot study to determine the antifungal activity of Promiseb Topical Cream after seven days of use in normal volunteers. Promius Pharma, LLC: Bridgewater, NJ; 2008. PSC0802.
3. Data on file. A multicenter pilot clinical study to evaluate the efficacy and safety of Promiseb in the management of mild to moderate seborrheic dermatitis in adults. Surrey, United Kingdom: Sinclair Pharmaceuticals, LTD; 2006.



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DR. ZACHARY

sure were not statistically significant, Dr. Zachary said.

A confirmatory phase III trial of 278 patients used a global eyelash assessment, digital image analysis, and patient-reported outcome measures to assess the efficacy of the product. At the end of 16 weeks, a statistically significant percentage of patients in the bimatoprost group had improvements in eyelash prominence, length, thickness, and darkness, compared with the vehicle group. The results of the randomized, double-blind, placebo-controlled study were consistent across age and race.

In terms of safety, four patients in the bimatoprost group and four patients in the control group discontinued due to adverse events. All of the treatment-related events were minor: eczematous change, irritant dermatitis, dry eye, eyelid erythema, and low intraocular pressure.

When used by glaucoma patients over long periods, bimatoprost resulted in darkening of the iris in some, Dr. Zachary said. Although this effect was not found in any of the cosmetic trials, patients should be informed of this possibility.

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Treatment results can be seen in these photos from Allergan’s clinical trial.