LATISSE® (bimatoprost ophthalmic solution) 0.03%

Skin care products, such as SkinMedica® *

Skin care treatments

Laser treatment(s)

Chemical peels

Microdermabrasion

Facials

Other _______________________

LATISSE® should only use

IPL laser therapy

Chemical peels

Microdermabrasion

Facials

Other _______________________

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BOTOX® Cosmetic (onabotulinumtoxinA) IMPORTANT INFORMATION

Indications
Glabellar Lines
BOTOX® Cosmetic (onabotulinumtoxinA) for injection is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT
Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and upper limb spasticity and at lower doses.

CONTRAINDICATIONS
BOTOX® Cosmetic is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin product or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Lack of Interchangeability between Botulinum Toxin Products
The potency Units of BOTOX® Cosmetic are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® Cosmetic cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

Spread of Toxin Effect
Please refer to Boxed Warning for Distant Spread of Toxin Effect.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatomic use of BOTOX® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

Please see additional Important Safety Information about BOTOX® Cosmetic on reverse side.

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

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 periocular 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.

Please see additional Important Safety Information for LATISSE® on reverse side.
**BOTOX Cosmetic (onabotulinumtoxinA) IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

**Serious Adverse Reactions With Unapproved Use**

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and for adjacent structures. In some of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

**Hypersensitivity Reactions**

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, angioedema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently, the causative agent cannot be reliably determined.

**Cardiovascular System**

There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease.

**Pre-existing Neuromuscular Disorders**

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized weakness, dysphagia, aspiration, or fainting. In these patients, appropriate medical evaluation and support should be readily available. These effects are likely to be exacerbated in patients with underlying unstable medical conditions (eg, seizures or infection) and in older patients who are debilitated by other medical conditions. The most commonly reported adverse events following injection of BOTOX® Cosmetic for unapproved uses are the unapproved uses of BOTOX®. The safety of BOTOX® for unapproved uses has not been established.

**Drug Interactions**

Administration of BOTOX® Cosmetic and amnoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the drug may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic may potentiate systemic anticholinergic effects.

The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX® Cosmetic.

**USE IN SPECIFIC POPULATIONS**

BOTOX® Cosmetic is not recommended for use in children or pregnant women. It is not known whether BOTOX® Cosmetic is excreted in human milk. Caution should be exercised when BOTOX® Cosmetic is administered to a nursing woman.

Please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

**LATISSE** (bimatoprost ophthalmic solution) 0.03% IMPORTANT SAFETY INFORMATION (continued)

**INDICATIONS**

**JUVÉDERM® XC injectable gel is indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).**

**JUVÉDERM VOLUMA® XC injectable gel is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.**

**ADVERSE EVENTS**

The most commonly reported side effects for **JUVÉDERM® XC injectable gel** were temporary injection-site erythema, edema, and swelling, which generally resolved without sequelae. They were consistently reported to occur within 3 days of injection and typically lasted for 3 to 14 days. The duration of these events was less than 7 days for 94% of patients.

**PRECAUTIONS**

**JUVÉDERM® XC and JUVÉDERM VOLUMA® XC should not be used in patients who have severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to gram-positive bacterial proteins or endotoxin.**

**WARNINGS**

**JUVÉDERM® XC injectable gel and JUVÉDERM VOLUMA® XC injectable gel must not be injected into blood vessels and should not be used in vascular-rich areas. Use in these areas, such as glabella and nose, has resulted in cases of vascular occlusion, embolization of the vessels, ischemia or infarction, or blindness. Symptoms of vessel occlusion and embolization include pain that is magnified when the patient is oriented to the particular injection site, immediate blanching extending beyond the injected area, and color changes that reflect ischemic tissue such as dusky or reticular appearance.**

**Product use at specific sites in which an active inflammatory process or infection is present should be deferred until resolved.**

**PRECAUTIONS**

**The safety for use in patients under 18 years for JUVÉDERM® XC, and for patients under 35 years or over 65 years for JUVÉDERM VOLUMA® XC, has not yet been established.**

**The safety and effectiveness of JUVÉDERM® XC for the treatment of anatomic regions other than those defined for JUVÉDERM® XC, have not been established.**

**The safety for use during pregnancy, in breastfeeding females, and in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentary disorders has not been studied.**

**Use with caution in patients on immunosuppressive therapy.**

**IMPORTANT SAFETY INFORMATION (continued)**

**PRECAUTIONS (continued)**

**Patients who are using products that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites.**

**If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or if the product is administered before the skin has healed completely, there is a possible risk of an inflammatory reaction at the treatment site.**

**Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events.**

**Dermal filler implantation carries the risk of infection. Standard precautions associated with injectable materials should be taken.**

**The safety of JUVÉDERM® XC injectable gel for use in patients with very thin skin in the mid-face has not been established.**

**The long-term safety of repeat treatments with JUVÉDERM VOLUMA® XC has not been established.**

**Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM® XC.**

**JUVÉDERM® XC should only be used by healthcare professionals who have appropriate experience and who are knowledgeable about facial anatomy and the product for use in the mouth (subcutaneous and/or supraperiosteal) injection for cheek augmentation.**

**ADVERSE EVENTS**

The most commonly reported side effects for **JUVÉDERM® XC injectable gel** were temporary injection-site edema, swelling, pain/tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. They were predominantly mild or moderate in severity, with a duration of 7 days or less.

Side effects for **JUVÉDERM® XC injectable gel** in > 5% of subjects were temporary injection-site tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. They were predominantly mild or moderate in severity, with a duration of 2 to 4 weeks.

To report an adverse reaction, please call Allergan Product Surveillance at 1-877-345-5372.

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

**JUVÉDERM® XC and JUVÉDERM VOLUMA® XC injectable gel products are available by prescription only.**