

## **JUVÉDERM® Collection of Fillers Important Information**

### **INDICATIONS**

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, for augmentation of the chin region to improve the chin profile, and for supraperiosteal injection to augment the temple region to improve moderate to severe temple hollowing in adults over the age of 21.

JUVÉDERM® VOLUX® XC injectable gel is indicated for subcutaneous and/or supraperiosteal injection for improvement of jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition.

JUVÉDERM® VOLLURE® 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) in adults over the age of 21.

JUVÉDERM® VOLBELLA® XC injectable gel is indicated for injection into the lips for lip augmentation and correction of perioral rhytids, and for the improvement of infraorbital hollowing in adults over the age of 21.

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

JUVÉDERM® Ultra XC injectable gel is also indicated for injection into the lips and perioral area for lip augmentation in adults over the age of 21.

### **IMPORTANT SAFETY INFORMATION**

#### **CONTRAINDICATIONS**

These products 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 lidocaine contained in these products.

#### **WARNINGS**

- Do not inject into blood vessels. Introduction of these products into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and, possibly, evaluation by an appropriate healthcare professional specialist should an intravascular injection occur

- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled

## **PRECAUTIONS**

- To minimize the risk of potential complications, these products should only be used by healthcare professionals who are knowledgeable about the anatomy and the product(s) for use in indicated area(s), and who have appropriate training in facial anatomy, vasculature, safe injection techniques, and identification and management of potential adverse events, including intravascular complications
- The potential risks of soft tissue injections should be discussed with patients prior to treatment to ensure they are aware of signs and symptoms of complications
- The safety and effectiveness for the treatment of anatomic regions other than indicated areas for each product have not been established in controlled clinical studies
- The safety for use of these products in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- The safety for use during pregnancy and in breastfeeding females has not been established
- The safety for use of JUVÉDERM® VOLUMA® XC has been established in patients between 35 and 65 years of age for cheek augmentation, 22 and 80 years of age for chin augmentation, and 32 and 82 years of age for improvement of temple hollowing
- The safety for use of JUVÉDERM® Ultra Plus XC and JUVÉDERM® Ultra XC in patients under 18 years, and the safety for use of JUVÉDERM® VOLUX® XC, JUVÉDERM® VOLLURE® XC, and JUVÉDERM® VOLBELLA® XC in patients under 22 years, has not been established
- Dermal filler implantation carries a risk of infection. Follow standard precautions
- Dermal fillers should be used with caution in patients on immunosuppressive therapy
- Patients taking medications that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients who experience skin injury near the site of implantation may be at a higher risk for adverse events
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or before skin has healed from a procedure prior to treatment, there is a possible risk of eliciting an inflammatory reaction at the injection site
- The safety for use of JUVÉDERM® VOLUMA® XC injectable gel in patients with very thin skin in the mid-face has not been established
- The safety of using a cannula with JUVÉDERM® VOLUMA® XC for cheek augmentation in patients with Fitzpatrick Skin Types V and VI or to improve temple hollowing has not been established

- JUVÉDERM® VOLUMA® XC was not evaluated in subjects with significant skin laxity of the chin, neck, or jaw in the chin augmentation study
- The effect of JUVÉDERM® VOLUMA® XC injection into the chin on facial hair growth has not been studied
- Patients may experience late-onset adverse events with injectable gel implants, and late-onset nodules with use of JUVÉDERM® VOLUMA® XC
- Based on preclinical studies, patients should be limited to 20 mL of any JUVÉDERM® injectable gel per 60 kg (132 lb) body mass per year. The safety of injecting greater amounts has not been established
- Injection of more than 9 mL of JUVÉDERM® VOLUX® XC for improvement of jawline definition has not been studied

## ADVERSE EVENTS

The most common reported side effects for JUVÉDERM® injectable gels were redness, swelling, pain, tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. For JUVÉDERM® VOLBELLA® XC, dryness was also reported. The majority were mild or moderate in severity.

**To report an adverse reaction with any product in the JUVÉDERM® Collection, please call Allergan® Product Support at 1-877-345-5372. Please visit [rxabbvie.com](http://rxabbvie.com) for more information.**

Products in the JUVÉDERM® Collection are available only by a licensed physician or properly licensed practitioner.

## KYBELLA® (deoxycholic acid) injection 10 mg/mL Important Information

### INDICATION

KYBELLA® (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

The safe and effective use of KYBELLA® for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

KYBELLA® is contraindicated in the presence of infection at the injection sites.

#### WARNINGS AND PRECAUTIONS

##### *Marginal Mandibular Nerve Injury*

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, were reported in 4% of subjects in the clinical trials; all cases resolved spontaneously (range 1-298 days, median 44 days). KYBELLA® should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve.

### *Dysphagia*

Dysphagia occurred in 2% of subjects in the clinical trials in the setting of administration-site reactions, eg, pain, swelling, and induration of the submental area; all cases of dysphagia resolved spontaneously (range 1-81 days, median 3 days). Avoid use of KYBELLA® in patients with current or prior history of dysphagia as treatment may exacerbate the condition.

### *Injection-Site Hematoma/Bruising*

In clinical trials, 72% of subjects treated with KYBELLA® experienced hematoma/bruising. KYBELLA® should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur.

### *Risk of Injecting into or in Proximity to Vulnerable Anatomic Structures*

To avoid the potential of tissue damage, KYBELLA® should not be injected into or in close proximity (1 cm-1.5 cm) to salivary glands, lymph nodes, and muscles. Care should be taken to avoid inadvertent injection directly into an artery or a vein as it can result in vascular injury.

### *Injection Site Alopecia*

Cases of injection site alopecia have been reported with administration of KYBELLA®. Onset and duration may vary among individuals and may persist. Consider withholding subsequent treatments until resolution.

### *Injection Site Ulceration, Necrosis, and Infection*

Injections that are too superficial into the dermis may result in skin ulceration and necrosis. Cases of injection site ulceration, necrosis, and infection have been reported with administration of KYBELLA®. Some cases of injection site infection have included cellulitis and abscess requiring antibiotic treatment and incision and drainage. Do not administer KYBELLA® into affected area until complete resolution.

## **ADVERSE REACTIONS**

The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

Please see KYBELLA® full [Prescribing Information](#).

## **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.

**Adverse Reactions:** The most frequently reported adverse events 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, hordeolum, hypersensitivity (local allergic reactions), lacrimation increased, madarosis and trichorrhesis (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), trichiasis, and vision blurred.

Please see LATISSE® full [Prescribing Information](#).

## **REVOLVE™ Advanced Adipose System Important Information**

### **INDICATIONS**

The REVOLVE™ Advanced Adipose System (REVOLVE™ System) is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. This system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation. REVOLVE™ System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

### **IMPORTANT SAFETY INFORMATION**

#### **CONTRAINDICATIONS**

Contraindications to autologous fat transfer include the presence of any disease processes that adversely affect wound healing, and poor overall health status of the individual.

## **WARNINGS**

REVOLVE™ System must be used within the same surgical procedure. Reuse of this device in the same patient in a subsequent surgical procedure, or for more than one patient, may result in infection and/or transmission of communicable diseases. Do not use the product if sterile packaging is damaged.

This device will not, in and of itself, produce significant weight reduction. This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease or obesity. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

## **PRECAUTIONS**

REVOLVE™ System is designed to remove localized deposits of excess fat through small incision and subsequently transfer the tissue back to the patient. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty and tissue transfer. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician. Results of this procedure may or may not be permanent. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect. Filling the device with adipose tissue over the maximum fill volume line can lead to occlusion of the mesh resulting in mesh tear.

## **ADVERSE EFFECTS**

Some common adverse effects associated with autologous fat transfer are asymmetry, over- and/or under-correction of the treatment site, tissue lumps, bleeding, and scarring. Potential adverse effects associated with REVOLVE™ System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction, and inflammation.

**REVOLVE™ System is available by prescription only.**

For more information, please see the [Instructions for Use \(IFU\)](#) and [User Manual](#) for REVOLVE™ System available at [www.allergan.com/REVOLVEIFU](http://www.allergan.com/REVOLVEIFU) or call 1.800.678.1605.

**To report an adverse reaction, please call Allergan at 1.800.367.5737.**

## **SkinMedica® Important Information**

SkinMedica® is a physician-dispensed, cosmetic, and non-prescription skin care product line.

Most SkinMedica® products are intended to meet the FDA's definition of a cosmetic product, an article applied to the human body to cleanse, beautify, promote attractiveness, and alter appearances. These SkinMedica® products are not intended to be drug products that diagnose, treat, cure, or prevent any disease or condition. These products have not been approved by the FDA and the statements have not been evaluated by the FDA.

SkinMedica® Total Defense + Repair Broad Spectrum Sunscreens (SPF 34 and SPF 34 Tinted) and Essential Defense Broad Spectrum Sunscreens (Everyday Clear SPF 47, Mineral Shield Tinted SPF 32, and Mineral Shield SPF 35) are over-the-counter drug products which are formulated and marketed pursuant to FDA's governing regulations set forth at 21 C.F.R. Part 352.

The PA rating System is used in Japan to classify UVA protection and is not an FDA requirement on sunscreens sold in the U.S.

SkinMedica® Purifying Foaming Wash is an over-the-counter drug product which is formulated and marketed pursuant to FDA's governing regulations set forth at 21 C.F.R. Part 333 Subpart D.

### **DiamondGlow® Treatment Important Information**

#### **Indication and Use**

The DiamondGlow® device is indicated for general dermabrasion of the skin and also delivers topical cosmetic serums onto the skin.

#### **IMPORTANT SAFETY INFORMATION**

DiamondGlow® is contraindicated in patients who have compromised skin quality including but not limited to, sunburned, chapped, irritated or broken skin, open wounds, active, weeping acne, cold sores, or herpetic ulcers. Ask your patient if they are pregnant or lactating or if they have any medical conditions, including allergies, and usage of topical medication on the area to be treated.

Typical side effects include a scratchy, stinging sensation during the treatment and temporary tightness, redness or slight swelling after the treatment. Rare serious side effects may also occur and include severe skin irritation and allergic reactions. Cease use of the device immediately if any of these serious side effects are observed.

Patients should be advised to use a sunscreen with a sun protection factor of 30 or higher following treatment.

Consult the DiamondGlow® User Manual for a complete list of Contraindications, Warnings, Precautions, and potential side effects.

#### **SkinMedica® Pro-Infusion Serums Disclaimer**

SkinMedica® Pro-Infusion Serums are intended to meet the FDA's definition of a cosmetic product, an article applied to the human body to cleanse, beautify, promote attractiveness, and alter appearances. These products are not intended to be drugs that diagnose, treat, cure, or prevent any disease or condition. These products have not been approved by the FDA and the statements have not been evaluated by the FDA.

### **SKINVIVE by JUVÉDERM® Important Information**

#### **INDICATIONS**

SKINVIVE by JUVÉDERM® injectable gel is indicated for intradermal injection to improve skin smoothness of the cheeks in adults over the age of 21.

## **IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

This product 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 lidocaine contained in this product.

### **WARNINGS**

- Do not inject into blood vessels. Introduction of this product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft-tissue fillers; for example, after insertion of the needle and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft-tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms: changes in vision, signs of a stroke, blanching of the skin, unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and, possibly, evaluation by an appropriate healthcare professional specialist should an intravascular injection occur
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled
- Injection site responses consist mainly of short-term inflammatory symptoms and generally resolve within 1 week. Refer to the ADVERSE EVENTS

### **PRECAUTIONS**

- To minimize the risk of potential complications, this product should only be used by healthcare professionals who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection
- Discuss all potential risks of soft tissue injections with patients prior to treatment and ensure patients are aware of signs and symptoms of potential complications
- Limit patients to 20 mL of any JUVÉDERM® injectable gel per 60 kg (130 lbs.) body mass per year. The safety of injecting greater amounts has not been established
- This product is intended for improving skin smoothness and fine lines of the cheeks. The safety and effectiveness of use in other areas of the body have not been established
- Injection of more than 6.0 mL of this product (initial and touch-up treatment combined) for improvement of skin smoothness and fine lines of the cheeks has not been studied
- As with all transcutaneous procedures, injections of the product carry a risk of infection

- The safety for use during pregnancy, in breastfeeding females, and in patients under 22 years has not been established
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, or pigmentation disorders has not been studied
- This product should be used with caution in patients on immunosuppressive therapy
- Patients taking medications that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients may experience late onset AEs with use of injectable gel implants, including this product
- This product should only be used by healthcare professionals who have appropriate experience and who are knowledgeable about the anatomy and the product for use in the face
- If laser treatment, chemical peel, or any other procedure based on active dermal response is considered after treatment, or before skin has healed from a procedure prior to treatment, there is a possible risk of eliciting an inflammatory reaction at the injection site

#### **ADVERSE EVENTS**

In clinical studies, injection site responses (ISRs) observed in >5% of treated subjects included redness, lumps/bumps, swelling, bruising, pain, tenderness, firmness, discoloration, and itching. Most ISRs were mild. Adverse events reported through postmarketing surveillance outside of the United States included inflammatory reaction, inflammatory nodule, unsatisfactory result, loss/lack of correction, allergic reaction, anxiety, vascular occlusion, infection, dry skin, increase/decrease in sensation, and abscess.

**To report an adverse reaction with SKINVIVE by JUVÉDERM®, please call the Allergan® Product Support Department at 1-877-345-5372. Please see Directions for Use or visit [SKINVIVEDFU.com](https://www.allergan.com/skinvivedfu) for more information.**

SKINVIVE by JUVÉDERM® is available only by a licensed physician or properly licensed practitioner.