Safety info - Indications, Important Safety Information, and Prescribing Information

BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

Indications

BOTOX® Cosmetic (onabotulinumtoxinA) is indicated in adult patients for the temporary improvement in the appearance of:

- Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity

- Moderate to severe lateral canthal lines associated with orbicularis oculi activity

- Moderate to severe forehead lines associated with frontalis activity

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 and approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses.

CONTRANDICATIONS

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 preparation 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 dermatologic use of BOTOX® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 40 Units (for forehead lines with glabellar lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines), and 64 Units (for simultaneous treatment of lateral canthal lines, glabellar lines, and forehead lines) have been reported. Patients or caregivers should be advised to seek immediate medical care if swallowing, speech, or respiratory disorders occur.

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/or adjacent structures. In several 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, soft-tissue edema, 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 causal 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, some 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.

Increased Risk of Clinically Significant Effects With 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 muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see Warnings and Precautions).

Dysphagia and Breathing Difficulties

Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see Boxed Warning).

Pre-existing Conditions at the Injection Site

Caution should be used when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Dry Eye in Patients Treated With BOTOX® Cosmetic

There have been reports of dry eye associated with BOTOX® Cosmetic injection in or near the orbicularis oculi muscle. If symptoms of dry eye (eg, eye irritation, photophobia, or visual changes) persist, consider referring patients to an ophthalmologist.

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

ADVERSE REACTIONS

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for glabellar lines were eyelid ptosis (3%), facial pain (1%), facial paresis (1%), and muscular weakness (1%).

The most frequently reported adverse reaction following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for forehead lines with glabellar lines were headache (9%), brow ptosis (2%), and eyelid ptosis (2%).

DRUG INTERACTIONS

Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin 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

There are no studies or adequate data from postmarketing surveillance on the developmental risk associated with use of BOTOX® Cosmetic in pregnant women. There are no data on the presence of BOTOX® Cosmetic in human or animal milk, the effects on the breastfed child, or the effects on milk production.

Please see BOTOX® Cosmetic full Prescribing Information including Boxed Warning and Medication Guide.

CoolSculpting® Important Information

Indications

The CoolSculpting® procedure is FDA-cleared for the treatment of visible fat bulges in the thigh, abdomen and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll), and upper arm in patients with a Body Mass Index (BMI) of ≤ 30 and in submental and submandibular areas in patients with a BMI of ≤ 46.2. It is also FDA-cleared to affect the appearance of lax tissue with submental area treatments.

Important Safety Information

CoolSculpting® is contraindicated in patients with cryoglobulinemia, cold agglutinin disease, or paroxysmal cold hemoglobinuria.

Ask your patient about any medical conditions including recent surgery, pre-existing hernia, and any known sensitivities or allergies.

During the procedure patients may experience sensations of pulling, tugging, mild pinching, intense cold, tingling, stinging, aching, and cramping at the treatment site. These sensations subside as the area becomes numb. Following the procedure, typical side effects include temporary redness, swelling, blanching, bruising, firmness, tingling, stinging, tenderness, cramping, aching, itching, or skin sensitivity, and sensation of fullness in the back of the throat after submental or submandibular area treatment.

Rare side effects may also occur. Paradoxical hyperplasia (visibly enlarged tissue volume in the treated area) may develop 2-5 months after treatment and requires surgical intervention for correction.

As with any medical procedure, a consultation should be done by a licensed healthcare professional to determine if the patient is a candidate for treatment. Consult the CoolSculpting® System User Manual for a complete list of Contraindications, Warnings, Precautions, and potential side effects. Treatment applications that deviate from the guidelines are not recommended.

CoolTone® Important Information

Indications

The CoolTone® device is indicated for improvement of abdominal tone, strengthening of the abdominal muscles, and development for firmer abdomen. CoolTone® is also indicated for strengthening, toning, and firming of buttocks and thighs.

Important Safety Information

CoolTone® treatment is contraindicated in placing the active applicator over metal, electrical, or electronic implants/devices in the treatment area like cardiac pacemakers, cochlear implants, intrathecal pumps, implanted defibrillators, implanted neurostimulators, drug pumps, or hearing aids.

CoolTone® is also contraindicated in placing the active applicator over menstruating uterus, over areas of the skin that lack normal sensation, and in patients with fever, malignant tumor, hemorrhagic conditions, epilepsy, recent surgical procedure, pulmonary insufficiency, or pregnancy.

CoolTone® should be used with caution in patients with Graves' disease, active bleeding disorders, or seizure disorders.

Women who are close to menstruation may find that it comes sooner, or cramping is increased or intensified with CoolTone® treatments, therefore, it is recommended to not undergo treatment during this time of the month.

CoolTone® should not be used in the heart or head areas, areas of growth plate, over the carotid sinus nerves, or over the neck or mouth. CoolTone® should not be applied over swollen, infected, inflamed areas or skin eruptions. Caution should be used for patients with suspected or diagnosed heart problems.

Ensure that persons with pacemakers are not present in vicinity of the device during treatment.

Common adverse effects may include, but may not be limited to muscular pain, temporary muscle spasm, temporary joint or tendon pain, and local erythema or skin redness.

Consult the CoolTone® User Manual for a complete list of Contraindications, Warnings, Precautions, and potential side effects. Treatment applications that deviate from the guidelines are not recommended.

JUVÉDERM® Collection of Fillers Important Information

INDICATIONS

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

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

JUVÉDERM® Ultra XC injectable gel is 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, 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 have appropriate training, experience, and knowledge of facial anatomy and product use in indicated areas

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 the mid-face, chin, and prejowl sulcus regions with JUVÉDERM® VOLUMA® XC; facial wrinkles and folds with JUVÉDERM® VOLLURE® XC, JUVÉDERM® Ultra Plus XC, and JUVÉDERM® Ultra XC; and the lips and perioral area with JUVÉDERM® VOLBELLA® XC and JUVÉDERM® Ultra XC have not been established in controlled clinical studies

The safety for use of these products during pregnancy, in breastfeeding females, and in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied

The safety for use of JUVÉDERM® VOLUMA® XC has been established in patients between 35 and 65 years of age in cheek augmentation and for patients between 22 and 80 years of age for chin augmentation

The safety for use of JUVÉDERM® Ultra Plus XC and JUVÉDERM® Ultra XC in patients under 18 years, and JUVÉDERM® VOLLURE® XC and JUVÉDERM® VOLBELLA® XC in patients under 22 years, has not been established

As with all transcutaneous procedures, dermal filler implantation carries a risk of infection

Use dermal fillers with caution in patients on immunosuppressive therapy

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

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

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 JUVÉDERM® VOLUMA® XC with cannula for cheek augmentation has not been established in patients with Fitzpatrick Skin Types V and VI

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 nodules with use of dermal fillers including JUVÉDERM® VOLUMA® XC

Patients may experience late onset adverse events with use of dermal fillers

ADVERSE EVENTS

The most commonly 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. For JUVÉDERM® VOLUMA® XC, most resolved within 2 to 4 weeks. For JUVÉDERM® VOLLURE® XC, JUVÉDERM® Ultra Plus XC, or JUVÉDERM® Ultra XC, most resolved within 14 days; and for JUVÉDERM® VOLBELLA® XC, most resolved within 30 days.

To report an adverse reaction with any product in the JUVÉDERM® Collection, please call Allergan at 1-800-433-8871. Please visit JuvedermDFU.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 and Necrosis

Injections that are too superficial into the dermis may result in skin ulceration and necrosis. Cases of injection site ulceration and necrosis have been reported with administration of KYBELLA®. 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 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), trichiasis, and vision blurred

Please see LATISSE® full Prescribing Information.

Natrelle® Breast Implants IMPORTANT SAFETY INFORMATION

WARNINGS

Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery

Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL

Patients receiving breast implants have reported a variety of systemic symptoms, such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases, and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement

INDICATIONS

Natrelle® Silicone-Filled Breast Implants and Natrelle INSPIRA® Breast Implants are indicated for women for the following:

Breast augmentation for women at least 22 years old for silicone-filled implants and breast augmentation for women at least 18 years old for saline-filled implants. This includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery

Breast reconstruction. This includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery

CONTRAINDICATIONS

Breast implant surgery should not be performed in:

Women with active infection anywhere in their body

Women with existing cancer or precancer of their breast who have not received adequate treatment for those conditions

Women who are currently pregnant or nursing

ADDITIONAL WARNINGS

See Boxed Warning in bold type above

Avoid damage during surgery: Care should be taken to avoid the use of excessive force and to minimize handling of the implant. Forcing of implants through too small an opening or applying concentrated localized pressure on the implants may result in localized weakening of the breast implant shell, potentially leading to shell damage and possible implant rupture. An incision should be of appropriate length to accommodate the style, size, and profile of the implants. Use care when using surgical instruments in proximity with the breast implant

Follow recommended fill volumes for saline implants to decrease possibility of shell wrinkling and crease-fold failure

PRECAUTIONS

Safety and effectiveness have not been established in patients with the following:

Autoimmune diseases (eg, lupus and scleroderma)

A compromised immune system (eg, currently receiving immunosuppressive therapy)

Planned chemotherapy or radiation following breast implant placement

Conditions or medications that interfere with wound healing and blood clotting

Reduced blood supply to breast tissue

Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery

ADVERSE EVENTS

Possible adverse events with breast implant surgery include implant rupture with silicone implants, implant deflation with saline-filled implants, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, infection, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. Other uncommon systemic conditions have been reported with breast implants.

For more information, please see the full Directions for Use at www.allergan.com/products.

To report a problem with Natrelle® Breast Implants, please call Allergan® at 1-800-624-4261.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Allergan ®.

REVOLVE™ Advanced Adipose System

Indications and Important Safety 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.

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

SkinMedica®

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, SPF 34 Tinted, and SPF 50+) 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.