
REVANESSE®
SHAPE™+

Patient Information Leaflet (1.0 mL and 1.2 mL)

If you have any questions about your treatment with Revanesse® Shape™+, or do not understand something about dermal filler injections, you should ask your doctor, or his or her staff, to explain. You should feel free to discuss your concerns openly with your doctor in order to better understand your options for treatment.

What is Revanesse® Shape™+?

Revanesse® Shape™+ is a cross linked hyaluronic acid gel. It is a colorless, odorless, transparent and aqueous gel of synthetic origin.

Composition

Cross-linked hyaluronic acid (High Viscosity)	25mg/ml
Lidocaine	0.3% w/w
In phosphate buffered saline	
(Cross linked with Butandiol-diglycidylether (BDDE))	

Application Range / Indications

Application: Medium to deep facial rhytides.

Medical Indications: The products are space-occupying tissue reconstructive materials composed of a hyaluronic acid gel that is indicated for restoration of volume loss from lipatrophy / lipodystrophy, and /or correction of contour deficiencies and anatomic deformities of either pathologic origin or after trauma, in facial soft tissue.

Intended patients are those desiring the correction of contour deficiencies and deformities in facial soft tissue, such as HIV-associated lipatrophy and lipodystrophy.

Cosmetic Indication: Revanesse® Shape™+ is indicated for the correction of facial rhytides, volume restoration, lip augmentation, skin hydration and contouring of depressions by injection into tissue.

How long does Revanesse® Shape™+ last?

Implantation life is dependent on depth and location of injection, and averages 6-12 months.

Are there any anticipated side effects I should be aware of?

There are no potential adverse reactions that may be delayed or occur immediately after the injection. These include but are not limited to:

- Injection-related reactions might occur, such as transient erythema, swelling, pain, itching, discoloration or tenderness at the injection site. These reactions may last for one week.
- Nodules or induration are also possible at the injection site.
- Poor product performance due to improper injection technique.

• Glabellar necrosis, abscess formation, granulomas, hypersensitivity, nasolacrimal duct obstruction and alagelia have all been reported with injections of hyaluronic acid products. It is important for physicians to take these reactions into account on a case by case basis.

Reactions thought to be of hypersensitivity in nature have been reported in less than one in every 1500 treatments. These have consisted of prolonged erythema, swelling and induration at the implant site.

These reactions have started either shortly after injection or after a delay of 2 – 4 weeks and have been described as mild or moderate, with an average duration of 2 weeks. Typically, this reaction is self-limiting and resolves spontaneously with time. However, it is imperative that patients with hypersensitivity type reactions contact their physician immediately for assessment. Patients with multiple allergic reactions should be excluded from the treatment.

Are there any reasons why I should not (contraindications) receive the Revanesse® Shape™+ injection?

- Contains lidocaine and is contraindicated for patients with a history of allergies to such material.
- Do not inject Revanesse® Shape™+ into eye contours (into the eye circle or eyelids).
- Pregnant women, or women during lactation should not be treated with Revanesse® Shape™+.
- Revanesse® Shape™+ is only intended for intradermal use and must not be injected into blood vessels. This may occlude and could cause an embolism.
- Patients who develop hypertrophic scarring should not be treated with Revanesse® Shape™+.
- Patients that have a known history of streptococcal disease.
- Contains trace amounts of gram positive bacterial proteins, and is contraindicated for patients with a history of allergies to such material.
- Never use Revanesse® Shape™+ in conjunction with a laser, intense pulsed light, chemical peeling or dermabrasion treatments.
- People under the age of 18 should not be treated with Revanesse® Shape™+.
- Patients with acne and /or other inflammatory diseases of the skin should not be treated with Revanesse® Shape™+.
- Patients with unattainable expectations.
- Patients with auto-immune disorders or under immunotherapy.
- Patients with multiple severe allergies.
- Patients with acute or chronic skin disease in or near the injection sites.
- Coagulation defects or under anti-coagulation therapy.
- Patients with sensitivity to hyaluronic acid.

It is imperative that patients with adverse inflammatory reactions that persist for more than one week report this immediately to their physician. These conditions may be treated as appropriate with corticosteroids, antibiotics or any other treatment options as determined by the healthcare professional.

Precautions

- Revanesse® Shape™+ should not be injected into an area that already contains another filler product as there is no available clinical data on possible reactions.

- Revanesse® Shape™+ should not be injected into an area where there is a permanent filler or implant.
- Hyaluronic acid products have a known incompatibility with quaternary ammonium salts such as benzalkonium chloride. Please ensure that Revanesse® Shape™+ never comes into contact with this substance or medical instrumentation that has come into contact with this substance.
- Revanesse® Shape™+ should never be used for breast enlargement, or for implantation into bone, tendon, ligament or muscle.
- Avoid touching the treated area for 12 hours after injection and avoid prolonged exposure to sunlight, UV, as well as extreme cold and heat.
- Until the initial swelling and redness have resolved, do not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold.
- If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another eruption of cold sores.
- If you are using aspirin, non-steroidal anti-inflammatory medications, St. John's Wort or High doses of Vitamin E supplements prior to treatment or any similar medications be aware that these may increase bruising and bleeding at the injection site.
- Based on a toxicological risk assessment for lidocaine, patients should be limited to 20 mL per 60 kg (130 lbs) body mass per annum. The safety of injecting greater amounts has not been established.
- The safety for use in patients under 18 years or over 65 years has not been established.
- Patients who are visibly ill, with bacterial or viral infections, influenza, or active fever should not be treated until a resolution of their symptoms.
- In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
- Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.

What happens before the procedure?

Your doctor will examine you, and will explain the procedure and the potential risks. You will be asked about your health, your medical history, and the medications you take and have recently taken. You should advise your doctor of any of your concerns before the procedure, and discuss any questions related to the procedure.

What happens during the procedure?

The doctor will prepare the area to be treated. There is some pain associated with the injection of the product. You should discuss your concerns about injection related pain with your doctor. The doctor will inject the filler, during which you may experience tenderness or a stinging sensation in the area of the injection. The procedure does not take long, often 15 to 30 minutes.

What should I expect after the procedure?

Following treatment, a cold compress or ice may be applied for any bruising or swelling at the injection site. You may also gently massage the area with constant pressure for several minutes. The most common side effects include: bruising, redness, swelling, pain, and itching. You should contact your doctor if you experience redness, itching or pain at the injection site for recommendations for over-the-counter treatment (such as Tylenol, Motrin or Benadryl). Most side effects occur shortly after injection and go away within two weeks. If you experience a reaction that lasts longer than two weeks, or what you think may be a delayed reaction to the product, contact your doctor.

You should seek immediate medical attention if you develop symptoms such as unusual pain, vision changes, a white appearance of skin near the injection site (blanching) or any other unexpected symptoms. While rare, unexpected symptoms include unusual pain, vision changes, or any signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, vision changes, face drooping, severe headache, dizziness, or confusion) during or shortly after the procedure. Additional side effects of dermal fillers less commonly reported include: infections, lumps and bumps, discoloration or change in pigmentation. It is rare for patients to have a delayed onset reaction or an infection such as cold sores (herpetic sores). Rare, but serious risks, of dermal fillers include: scarring, blurred vision, partial vision loss, and blindness if the dermal filler is inadvertently injected into a blood vessel. In occasionally rare cases, there have been reports of unintentional injection of the product into a blood vessel with dermal filler products. It is recommended that doctors take care to avoid injection into blood vessels (especially around the forehead, nose and eye area) for these reasons, allergic reaction that may lead to a severe reaction (anaphylactic shock) that requires emergency medical help.

Medical Device Incident Reporting:

Serious Medical Device Incidents are to be reported to: Prollemium Medical Technologies Inc. at medicalaffairs@prollemium.com and TGA at <https://www.tga.gov.au/safety/reporting-problems/report-adverse-event-or-problem-consumers>

Patient Assistance Information:

If you require immediate assistance, please contact your health care provider. For further assistance, please contact Prollemium Medical Technologies Inc. at: T: 1.866.353.2015 | F: 1.866.676.6716 | I: 905.508.1469 (local) | F: 905.508.6716 (local) E: info@prollemium.com | www.prollemium.com

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