

## *Press Kit: Primary Messaging*

The following points outline three key differentiators of Revanesse® Versa™. Using these points as a guideline and basis for content creation will help ensure product claims are accurate. Please ensure adherence to the approved Prolenium Medical marketing guidelines when preparing promotional materials related to Revanesse® Versa™. Selected examples of acceptable advertising claims appear below. For the full Important Safety Information see page 2.

1. Revanesse® Versa™ is based on a formula that has been sold worldwide since 2011 and just recently received FDA approval in the US. The original formula has sold over 1 million syringes with zero reported instances of nodules or granulomas.

*Revanesse® Versa™ quality is the product of unyielding research and development, resulting in a proprietary formula which has been demonstrated to be both safe and effective.*

**IMPORTANT SAFETY INFORMATION TO INCLUDE:**

The most common side effects include: bruising, redness, swelling, pain, and itching.

2. Our North American factory uses a proprietary, small-batch manufacturing process, that results in a spherical and uniform particle which provides optimal smoothness and volume. The particle is easily accepted by the body and was shown to produce less swelling in a recent clinical study.

*Revanesse® Versa™ has been engineered throughout its product realization cycle by teams of physicians, chemists and engineers. The result is a dermal filler of outstanding quality.*

**IMPORTANT SAFETY INFORMATION TO INCLUDE:**

Injection site swelling (47.2% [77/163] with Revanesse® Versa™, 71.2% [116/163] with Comparator)

3. Revanesse® Versa™ is formulated to be balanced with the water content of natural skin. This means the treatment doesn't release or absorb surrounding water and minimizes concern of over or under treatment.

*Our formula has been scientifically optimized to produce remarkable treatment outcomes.*

**IMPORTANT SAFETY INFORMATION TO INCLUDE:**

Swelling: Swelling is expected and may take several days to a week to resolve. It is unusual but medical treatment may be necessary if swelling is slow to resolve.

## IMPORTANT SAFETY INFORMATION

### What is Revanesse Versa?

Revanesse Versa is hyaluronic acid dermal filler. Hyaluronic acid is a naturally occurring substance that is found within the body. It may be produced by bacteria and purified for use as injectable soft tissue filler in order to correct the appearance of facial wrinkles and creases, (nasolabial folds). The product is approved for use in the U.S. by the Food and Drug Administration for the cosmetic treatment of facial wrinkles and creases.

### Are there any warnings I should be aware of?

If you have an adverse inflammatory reaction, such as redness, pain and swelling that persist for one week or more after treatment with Revanesse Versa, you should report this immediately to your doctor. If you are under the age of 22 you should not be treated with Revanesse Versa.

**Warning:** One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment, you should notify your health care practitioner immediately.

### Are there any reasons why I should not (contraindications) receive the Revanesse Versa injection?

You should not be treated with Revanesse Versa if you:

- are pregnant or breastfeeding, as the safety of these products for use during pregnancy, or in women who are breastfeeding, has not been studied
- have a history of hypertrophic scarring or keloid formation
- have evidence of scars at the intended treatment sites
- have acne and / or other inflammatory diseases of the skin, such as rosacea, seborrheic dermatitis, and psoriasis,
- have allergic history including:
  - severe allergic reactions (anaphylaxis),
  - heightened immune responses to common allergens, especially inhaled allergens and food allergens (atopy),
  - allergy to natural rubber latex,
  - allergy to hyaluronic acid products,
  - Streptococcal proteins or have plans to undergo administration of graded doses of allergens (desensitization therapy) during treatment with Revanesse Versa.
- have acute or chronic skin disease, such as seborrheic dermatitis or rosacea, in or near the injection sites, or any infection or unhealed wound of the face
- are under concomitant anticoagulant therapy, antiplatelet therapy, or have a history of bleeding disorders, clotting disorders such as hemophilia or connective tissue disorders such as systemic lupus erythematosus

You should never use Revanesse Versa in conjunction with a laser, intense pulsed light, chemical peeling or dermabrasion treatments, or with Over-the-counter (OTC) wrinkle products or prescription wrinkle treatments within 4 weeks (28 days) prior to treatment, as there is a possible risk of inflammation at the treatment site if these procedures are performed before treatment.

### What are the risks?

- **Bleeding and Bruising:** Bleeding is usually minimal and resolves within a few minutes. It is possible to have a bleeding episode from the injection of the local anesthesia or filler that requires treatment, but it is unusual. Bruising in the area is also an expected reaction and can take up to a week to resolve.
- **Swelling:** Swelling is also expected and may take several days to a week to resolve. It is unusual but medical treatment may be necessary if swelling is slow to resolve.
- **Pain:** Some discomfort is expected with injections but usually lasts less than a day.

Other risks that are less likely, but may occur, include the following: Acne-like skin eruptions, Skin sensitivity (rash, itching, tenderness), Skin infection, Damage to nerves or blood vessels, Skin lumpiness, Scarring, Skin necrosis (death of the skin), Hyperpigmentation (darkening of the skin), Reactivation of herpes infection (blisters or skin sores).

As with using any dermal filler, there is a risk of allergic reaction. If you have a very serious allergic reaction (anaphylactic shock) you may require emergency medical help and be at risk of death. Some symptoms of allergic reactions are: a rash, having a hard time breathing, wheezing when you breathe, sudden drop in blood pressure, swelling of the face, fast pulse, sweating, dizziness or fainting, inability to breathe without assistance, a feeling of dread.

One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities or blindness.

## **Side Effects:**

Ask your doctor if you have questions about any of the side effects, and please tell your doctor or your doctor's staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel, whether or not you think these problems are related to the products.

The most common side effects include: bruising, redness, swelling, pain, and itching.

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, visual changes, face drooping, severe headache, dizziness, or confusion) during or shortly after the procedure.

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.

## **Patient Assistance Information:**

If you have further questions, please contact:  
Prolenium Medical Technologies, Inc.  
1-866-353-3015 or +1-905-508-1469 (internationally)  
9 AM and 5 PM EST Monday through Friday.

**For more information about Revanesse Versa, please see the Directions for Use or speak to your health care provider.**

## *Press Kit: Detailed Information*

### **The Product:**

For those who are looking to take control of the signs of aging, Revanesse® Versa™ is a multi-purpose dermal filler that leverages state of the art production methods, optimal ingredients and rigorous quality testing to provide remarkable results. Revanesse® is based on a tried and tested formula, with over 1 million syringes used worldwide since 2002.

### **The Manufacturer:**

Prollenium® works in tandem with a worldwide network of respected aesthetic physicians and nurses to develop and produce premium dermal fillers, facial aesthetic & skincare products that are aimed at providing an excellent experience and optimized results. Our commitment to ensuring that our products are every bit as safe as they are effective, is apparent in our small-batch manufacturing process and high quality standards. We are driven by the belief that our patients and providers deserve the best.

Prollenium® is an established company out of Aurora Ontario, Canada that is dedicated to becoming a global leader in injectable biomaterials. Prollenium® fillers are made in Canada and distributed in over 90 countries worldwide. We have been selling direct in the Canadian market for more than 4 years. The Revanesse® line of dermal fillers has achieved an 18% market share amongst a variety of competitors- an additional 6 to what is currently in the US market. Prollenium® has sold over a million syringes of Revanesse® worldwide.

### **The Clinical Advantages:**

**The Spherical Particle:** Through an advanced wet-milling, refinement technique, Revanesse® Versa™ achieves a high degree of spherical particle shape and uniformity, compared to other HA dermal fillers. This is significant because spherically shaped particles have less surface area, so they are more easily accepted and integrated into the body. Since the particles are not as easily recognized as foreign, the product's duration is increased.

**Proprietary Formula:** The HA in Revanesse® Versa™ is efficiently cross-linked allowing the formula to be manufactured with less BDDE (which is thought to increase post injection swelling) and more HA (25 micrograms per ML).

**Designed for Precise Application:** The Revanesse® Versa™ formula is designed to be balanced with the skin's natural water content. This means our treatment is optimized to stay true to your desired volume and placement.

**Less Swelling:** In a recent FDA study, Restylane® was shown to produce swelling 24% more often than Revanesse® Versa™. Our lower rate of swelling means many patients are able to get back to their lives almost immediately after the treatment.

Injection site swelling (47.2% [77/163] with Revanesse® Versa™, 71.2% [116/163] with Comparator)

## **The Manufacturing Advantages:**

**Individually Inspected:** Revanesse® Versa™ is manufactured in North America and adheres to global and FDA safety standards. Extensive tests are performed on all of the raw materials used to produce Revanesse® Versa™ and strict controls are used during the manufacturing process. Each batch is meticulously tested in-house. As a final test, each and every syringe is individually inspected, to ensure that it is safe and effective.

**Small-batch Production:** We take every possible step to ensure that Revanesse® Versa™ is manufactured to the highest quality standard. We avoid mass production methods and choose to produce our product in small batches to ensure that it adheres to the highest quality standards and is always delivered fresh.

**Designed for Safety:** Our biocompatible and biodegradable formula breaks down naturally in the body over time.

## **Commitment to Volume:**

A critical factor in achieving optimal results with dermal fillers is to use the correct amount. This is why we support full correction with rewards programs for consumers and education for providers to ensure that those who use Revanesse® Versa™ always realize its full potential. We make it easier for patients and providers to access more product for each treatment, because we believe that everyone deserves the best.

## **The Rewards App:**

In order to thank our customers and support our providers, we've developed Prollenium® Elite, a customer rewards app that delivers the visionary insight, premium quality and optimized usability you'd expect from Prollenium®.

Patients can use Prollenium® Elite to:

- Select a preferred provider.
- Receive updates on provider feature sales and promotions.
- Get instant notifications about exclusive offers and events.
- Earn and redeem valuable rewards.

Providers can use Prollenium® Elite to:

- Engage with and reward clients.
- Issue unique rewards, only redeemable at their location, to reward and promote patient loyalty

Create entirely customized promotions that promote their full line of products and services  
Use push notifications to connect with clients how and when they want

The app is incredibly easy and user friendly for both practices and patients. The whole process is seamless, instant, and is completely controlled by the patient's phone and QR (quick response) scan codes. It cuts out paperwork and the need to generate coupons.

## **Testimonials:**

"We have injected over 1000 syringes of Versa in my clinic without any significant side effects. No delayed onset nodules or inflammatory reactions. Versa is a fabulous Candian product! The results from the FDA PMA clinical trial agree with the results that I have seen in hundreds of patients that have now been injected...less swelling and smoother results." –Dr. Martin Braun

*"Just what I wanted" –Ellen, 60*

*"The positive, instant results make the treatment very desirable." –Krista, 42*

*"The results are incredible, very natural and even." –Anne, 51*