#injectableHA

EVOLYSSE™

The First Innovation in HA Technology in Over a Decade

- The First Injectable HA made with Cold-X™ Technology which uses near-freezing temperatures designed to preserve the natural structure of the HA molecule
- The First injectable HA to demonstrate non-inferiority and statistical superiority at 6 months vs Restylane-L in a pivotal trial*
- The First Injectable HA to Recognize Weight Loss in the Patient Label as a Factor in Wrinkle Formation

*The primary endpoint was non-inferiority vs control at 6 months as determined by a photographic review panel using the WSRS. Non-inferiority and statistical superiority at 6 months based on the primary endpoint analysis for Evolysse Form (95% CI [-0.500, -0.032], $p<0.001$) and Evolysse Smooth (95% CI [-0.416, -0.019], $p<0.001$).

EVOLYSSE™ byevolus

INDICATIONS AND IMPORTANT SAFETY INFORMATION

EVOLYSSE™ SMOOTH and EVOLYSSE™ FORM are indicated for dermal and subdermal injection to correct moderate to severe dynamic facial wrinkles and folds (such as nasolabial folds) in adults 22 years and older.

IMPORTANT SAFETY INFORMATION

Contraindications

These products should not be used in patients who have severe allergies manifested 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.

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 during injection (e.g., after insertion of the needle and just before injection, withdraw plunger rod slightly to aspirate and verify the needle is not intravascular, inject the product slowly, 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, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate healthcare specialist should an intravascular injection occur.
- Defer use of these products at specific sites with an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection until the underlying process has been controlled.

Precautions

- EVOLYSSE products should only be used by healthcare professionals who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the injection site.
- Discuss all potential risks of EVOLYSSE injections, including signs of potential complications, with patients prior to treatment.
- The safety and effectiveness for the treatment of other areas have not been established in controlled clinical studies.
- The safety for use in sites with proximity to other implants (including permanent implants) has not been studied.
- Injection into patients with a history of facial herpetic eruption may reactivate herpes infection.
- The safety for use during pregnancy, breastfeeding, or 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.
- Use with caution in patients with an autoimmune disorder or on immunosuppressive therapy.
- Patients taking medication that can prolong bleeding (e.g., aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at injection sites.
- Treatment carries a risk of infection. Follow standard precautions.
- If laser treatment, chemical peeling, or any other procedure based on an active dermal response is considered after treatment, or before the skin has healed after such procedures, there is a possible risk of eliciting an inflammatory reaction at the implant site.
- Patients may experience late onset adverse events with use of soft tissue fillers.
- EVOLYSSE products contain lidocaine. Use with caution if local anesthetics are used concurrently.
- Injection of EVOLYSSE products too superficially or in areas with limited soft tissue support or thin skin may result in skin contour irregularities, palpable lumps, and/or bluish discoloration.
- Advise patients to minimize exposure of the treated area to extreme temperatures (e.g., intense cold or sauna) until any local inflammation has resolved.

Adverse Events

The most common reported side effects for EVOLYSSE products were tenderness, swelling, lumps, bruising, redness, pain, discoloration, and itching. The majority were mild or moderate in severity.

To report an adverse event with any EVOLYSSE product, please contact Evolus Customer Experience at 1-877-386-5871. Please visit www.EvolusRx.com for more information.

EVOLYSSE products are available only by a licensed physician or properly licensed practitioner.

Please see Directions for Use at www.EvolusRx.com

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