RHA® Collection of Fillers

Indications

The RHA® Collection of resilient hyaluronic acid (HA) fillers includes RHA Redensity™, RHA® 2, RHA® 3 and RHA® 4.

RHA Redensity™ is indicated for injection into the dermis and superficial dermis of the face, for the correction of moderate to severe dynamic perioral rhytids in adults 22 or older. RHA® 2 and RHA® 3 are indicated for injection into the mid-to-deep dermis for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds in adults 22 or older. RHA® 4 is indicated for injection in the deep dermis to superficial subcutaneous tissue for the correction of moderate to severe dynamic facial wrinkles and folds, such as nasolabial folds in adults 22 or older.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not use in patients who have severe allergies, marked by a history of anaphylaxis or multiple severe allergies, or in patients with a history of allergies to gram-positive bacterial proteins or local anesthetics of the amide type, such as lidocaine. Do not use in patients with bleeding disorders.

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, or 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 or infection is present should be deferred until the underlying process has been controlled.

Precautions

These products should only be used by healthcare professionals who have appropriate training, experience, and knowledge of facial anatomy.

Discuss the potential risks of soft-tissue injections with your patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.

The safety and effectiveness for the treatment of anatomic regions other than the labeled indications have not been established in controlled U.S. clinical studies.

As with all transcutaneous procedures, dermal filler implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.

The safety for use in sites in the presence of other implants, during pregnancy, in breastfeeding females, and in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied.

Use with caution in patients on immunosuppressive therapy.

Patients who are using products that can prolong bleeding (such as thrombolytics, anticoagulants, or inhibitors of platelet aggregation) may experience increased bruising or bleeding at treatment sites.

Patients with a history of herpetic eruptions may experience reactivation of the herpes.
There is a possible risk of inflammation at the implant site if laser treatments or a chemical peel are performed after treatment.
Use as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, safety, homogeneity, or performance of the product.
For single patient use. Do not reuse a syringe between two treatments and/or between two patients. Do not resterilize.

Adverse Events
The most commonly reported side effects were firmness, redness, tenderness, swelling, lumps/bumps, bruising, discoloration, pain and itching. Most of these events were mild or moderate and resolved within 14 days. Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own. To report an adverse reaction with any RHA® product, please call Revance at (877) 373-8669.
RHA-P-002436.2

REFERENCES

RHA Redensity™ Directions for Use. Nashville, TN: Revance Therapeutics, Inc, 2022.