

Instructions for Use

The Revanesse® Family of Products

Revanesse®, Revanesse® Ultra, Revanesse® Pure, ReDexis®, ReDexis® Ultra

Revanesse® Ultra
Cross Linked Hyaluronic Acid ~ High Viscosity



COMPOSITION

Hyaluronic Acid (high viscosity) 25 mg

DESCRIPTION

Revanesse® Ultra is a colorless, odorless, transparent and aqueous gel, of synthetic origin. The gel is stored in a pre-filled disposable syringe. Each box contains a 1ml syringe of Revanesse® Ultra along with a sterilized 30g 13mm needle.

APPLICATION RANGE / INDICATIONS

Revanesse® Ultra is a cross linked hyaluronic acid gel that is indicated for the treatment of medium to deep lines and wrinkles of the face, lipoatrophy and facial wasting by injection into the middle part of the dermis layer. Implantation life is dependant on depth and location of injection, and averages 6-12 months.

ANTICIPATED SIDE EFFECTS

Physicians must inform patients that with every injection of Revanesse® Ultra there are potential adverse reactions that may be delayed or occur immediately after the injection. These include but are not limited to:

- **I**njection-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.
- **N**odules or induration are also possible at the injection site.
- **P**oor product performance due to improper injection technique.
- **G**labellar necrosis, abscess formation, granulomas and hypersensitivity 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.

CONTRAINDICATIONS

- **D**o not inject Revanesse® Ultra into eye contours (into the eye circle or eyelids).
- **P**regnant women, or women during lactation should not be treated with Revanesse® Ultra.
- **R**evanesse® Ultra should never be injected into blood vessels.
- **P**atients who develop hypertrophic scarring should not be treated with Revanesse® Ultra.
- **P**atients that have a known history of streptococcal disease.
- **N**ever use Revanesse® Ultra in conjunction with a laser, intense pulsed light, chemical peeling or dermabrasion treatments.
- **P**eople under the age of 18 should not be treated with Revanesse® Ultra.
- **P**atients with acne and / or other inflammatory diseases of the skin should not be treated with Revanesse® Ultra.
- **P**atients with unattainable expectations.

► It is imperative that patients with adverse inflammatory reactions that persist for more than one week report this immediately to their physician. These conditions should be treated as appropriate (ie: corticosteroids or antibiotics). All other types of adverse reactions should be reported directly to the authorized distributor of the Revanesse® Ultra family of products and / or to Prollenium Medical Technologies Inc. directly.

ADMINISTRATION & DOSAGE

- **R**evanesse® Ultra should only be injected by or under the direct supervision of qualified physicians who have been trained on the proper injection technique for filling facial wrinkles.
- **B**efore patients are treated they should be informed of the indications of the device as well as its contraindications and potential undesirable side effects.
- **T**he area to be treated must be thoroughly disinfected.
- **B**e sure to inject only under sterile conditions.
- **R**evanesse® Ultra and needles packaged with it are for single use only. Do not re-use.
- **K**eep the product at room temperature for 30 minutes prior to injection.
- **I**nject slowly into the dermis using the linear tracking injection technique with the 30g needles that have been provided. The amount of Revanesse® Ultra that is injected per wrinkle will depend on its severity.
- **I**f the skin turns a white color (blanching), the injection should be stopped immediately and the area should be massaged until the skin returns to its normal color.
- **B**efore injecting, press on the plunger of the syringe until a small drop is visible at the tip of the needle.

PRECAUTIONS

- **R**evanesse® Ultra should not be injected into an area that already contains another filler product as there is no available clinical data on possible reactions.
- **R**evanesse® Ultra should not be injected into an area where there is a permanent filler or implant.
- **H**yaluronic acid products have a known incompatibility with quaternary ammonium salts such as benzalkonium chloride. Please ensure that Revanesse® Ultra never comes into contact with this substance or medical instrumentation that has come into contact with this substance.

▶ **Note: the correct injection technique is crucial to treatment success & patient satisfaction. Revanesse® Ultra should only be injected by a practitioner qualified according to local laws and standards.**

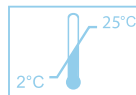
- **A**void touching the treated area for 12 hours after injection and avoid prolonged exposure to sunlight, UV, as well as extreme cold and heat.
- **U**ntil the initial swelling and redness have resolved, do not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold.
- **I**f you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another eruption of cold sores.
- **I**f you are using aspirin or any similar medications be aware that these may increase bruising and bleeding at the injection site.

WARNINGS



- ▶ Confirm that the seal on the box has not been broken and sterility has not been compromised.
- ▶ Confirm that the product has not expired.
- ▶ Product is for single use only; do not re-use.

SHELF LIFE & STORAGE



Expiry is indicated on each individual package. Store between 2°-25° C, and protect from direct sun light and freezing.

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Lot number/batch number



Read instruction/product insert before use



Expiry date



Do not reuse – For single use only



Needle Sterilization by EO



Moist heat sterilization



Storage temperature (store between the temperatures of)



Manufacturing date



CE marking according to MDD 93/42/CEE
0086 is the number of the notified body