MEDICA DEPOT

RESTYLANE® VOLYME with Lidocaine Product Specifications

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INSTRUCTIONS FOR USE

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I. COMPOSITION

Cross-linked hyaluronic acid	20 mg/mL
Lidocaine hydrochloride	3 mg/mL
Phosphate buffered saline pH 7	qs ad 1 mL

II. DESCRIPTION

Restylane® Volyme™ is a sterile, biodegradable, transparent gel of non-animal cross-linked hyaluronic acid with the addition of lidocaine hydrochloride 3 mg/mL. The gel is supplied in a prefilled plastic syringe. The contents of the syringe are sterilized using moist heat. The syringe is packaged individually in a blister, with two 27G x ½" Ultra thin wall needles. The needles have been sterilized using irradiation. The product is for single use only. To ensure traceability the package includes patient record labels that should be attached to patient records.

III. INTENDED USE

The product is intended to augment the volume of facial tissues. It is recommended to be used for the correction of facial volume, for instance cheeks and chin. Depending on the area to be treated and the tissue support, the product should be injected into the supraperiostic zone or subcutis. Lidocaine is added to the formulation to diminish the pain resulting from the injection during the treatment.

The product is only intended to be used by authorized personnel in accordance with local legislation, trained in the appropriate injection techniques. Before the first treatment session, it is recommended to contact your local Galderma representative or Restylane distributor for information about training opportunities.

IV. MODE OF ACTION

The product adds volume to the tissue thereby restoring the skin contours of the face to the desired level. The volume and lifting capacity originate from the ability of cross-linked hyaluronic acid to bind water.

V. CONTRAINDICATIONS

- Patients presenting with known allergy to hyaluronic acid filler or amide local anaesthetics.
- Patients presenting with porphyria.

VI. WARNINGS

- Do not use where there is active disease, such as inflammation, infection or tumours, in or near the intended treatment site.
- Do not inject intravascularly. As for other injectable medical devices, inadvertent injection into or next to blood vessels could potentially lead to vascular occlusion or compression, ischemia and necrosis.
- Do not use in patients with bleeding disorders or in patients who are taking thrombolytics or anticoagulants.
- Do not inject this product into an area where an implant other than hyaluronic acid has been placed.
- Do not resterilize.
- Do not mix with other products.

VII. PRECAUTIONS FOR USE

General considerations relevant to injectable medical devices

- Knowledge of the anatomy of treatment site and special caution are required in order to avoid perforation or compression of vessels, nerves and other vulnerable structures.
- Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be observed.
- Special caution should be exercised when treating areas with limited collateral circulation, due to increased risk of ischemia.
- Special caution should be exercised in treating facial areas with limited soft tissue support or soft tissue cover, such as the periorbital area, to avoid formation of palpable lumps.
- Patients with pre-existing pigmented dark lower eye lid circles, thin skin and pre-existing tendency toward oedema formation are not suitable candidates for treatment of the lower periorbital region.
- Patients using immunosuppressants are not suitable candidates for treatment.
- Special caution should be exercised in treating patients with a tendency to form hypertrophic scars or any other healing disorders.

- Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.
- Patients who are using substances that affect platelet function, such as aspirin and nonsteroidal anti-inflammatory drugs may, as with any injection, experience increased bruising or bleeding at injection sites.
- Patients with unattainable expectations are not suitable candidates for treatment.
- Do not use the product if the package is damaged.
- Do not use the product if the contents of the syringe are cloudy.

Specific considerations relevant to the use of this product

- The product is not indicated for injection other than into the supraperiostic zone or subcutis.
- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine is used concurrently. High doses of lidocaine (more than 400 mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.
- Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g., certain anti-arrhythmics, since the systemic toxic effects can be additive.
- Lidocaine should be used cautiously in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.
- If the product is injected too superficially this may result in visible lumps and/or bluish discoloration.
- The patient must avoid exposing the treated area to heat (sun bathing, sauna, steam baths, etc.) or extreme cold until any signs of local inflammation have disappeared.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is performed after treatment with this product there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if the product is administered before the skin has healed completely after such a procedure.
- At each treatment session a maximum dosage of 2 mL per treatment site is recommended.
- This product has not been tested in pregnant or breastfeeding women.
- Do not use in children.

VIII. ADVERSE EVENTS

Patients must be informed of the potential risks and adverse events related to the injection procedure and to the use of this product.

The following post market adverse events have been reported (non-exhaustive list): angioedema, atrophy/scaring, blisters, bruising, capillary disorders such as telangiectasia, dermatitis, discoloration, erythema, hypersensitivity, induration, infection, inflammation, ischemia/necrosis, mass, neurological symptoms such as paraesthesia, pain/tenderness, papules/nodules, pruritus, reactivation of herpes infection, short duration of effect, swelling and urticaria.

Other potential adverse events that have been reported following injection of hyaluronic acid gels in general and may occur when using the product include the following: abscess, acne, device dislocation, fistula, granuloma, rash and visual disturbance.

Injection related adverse events such as bruising, erythema, itching, swelling, pain and tenderness generally resolve spontaneously within one week after injection.

Vascular compromise may occur due to an inadvertent intravascular injection or as a result of vascular compression associated with implantation of any injectable product. This may manifest as ischemia or necrosis at the implant site or in the area supplied by the blood vessels affected; or rarely as ischemic events in other organs due to embolisation. Following facial aesthetic treatments isolated rare cases have been reported regarding ischemic events affecting the eye leading to visual loss, and the brain resulting in cerebral infarction. After injections of the nose ischemia/necrosis may occur, especially in patients who had prior rhinoplasty.

Symptoms of inflammation at the implant site commencing either shortly after injection or after a delay of up to several weeks have been reported. In case of unexplained inflammatory reactions infections should be excluded and treated if necessary since inadequately treated infections may

progress into complications such as abscess formation. Treatment using only oral corticosteroids without concurrent antibiotic treatment is not recommended. In case of persistent or recurrent inflammatory symptoms, consider removal of the product by aspiration/drainage, extrusion or enzymatic degradation (use of hyaluronidase has been described in scientific publications). Before any removal procedure is performed, the swelling may be reduced by using e.g. NSAID for 2-7 days or a short course of corticosteroids for less than 7 days, in order to more easily palpate any remaining product.
For patients who have experienced medically important adverse events, a decision for retreatment should take into consideration the cause and severity of previous reactions.
For reporting adverse events contact your local Galderma representative or distributor for this product.

IX. TREATMENT PROCEDURE

Inform the patient about the precautions to be taken, the expected result and the possible adverse events.
It is important to use a sterile, appropriate needle or blunt cannula. Suitable needles (27G x ½" Ultra thin wall) are supplied with the syringe in the blister pack. As an alternative, a blunt thin walled cannula with a recommended size of 27G or wider can be used.
Assembling the needle/cannula and syringe:

- use surgical gloves
- unscrew the protective cap from the stopper
- carefully remove the stopper from the syringe
- firmly screw the needle/cannula with its shield onto the tip of the syringe
- remove the shield just before injection

Cleanse the area to be treated with an antiseptic and allow it to dry before injection.
To avoid breakage of the needle/cannula, do not attempt to bend or otherwise manipulate it before or during treatment.
Before injecting the product, depress the plunger rod carefully until a small droplet is visible at the tip of the needle/cannula.
Align the bevel of the needle by turning the syringe on its axis. If a blunt cannula is used, an entry point is made in the skin, for example with a sharp needle of appropriate size.
Aspiration is recommended prior to injection in order to reduce the risk of inadvertent injection into a blood vessel. Inject slowly. During injection, keep the side hole of the cannula facing downwards, away from the skin surface.
Inject the gel by gently pressing down on the plunger rod with the thumb or palm of the hand.
Choose from linear threading or cross-hatching injection techniques.
It is recommended to change needle/cannula for each new treatment site.
Defects should be fully corrected, but not overcorrected, at each treatment session.
If "blanching" of the skin is observed as a result of over-superficial injection, the whitened area should be massaged gently until it returns to a normal colour.
Gently massage the treated area after injection.
The syringes and needles/cannulas must be discarded immediately after use in accordance with accepted medical practice and applicable national, local or institutional guidelines. The product shall not be reused due to risk for contamination of unused material and the associated risk including infection. Standard precautions apply when handling the needles. Needles should be disposed in a container dedicated for sharp devices.

X. SHELF LIFE AND STORAGE

Do not use after the expiry date indicated on package. Store up to 25°C. Protect from freezing and sunlight.

XI. MANUFACTURER

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