Disclaimer:

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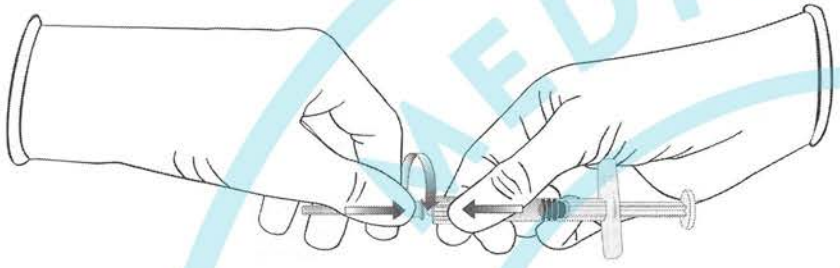
Use the thumb and forefinger to hold firmly around both the glass syringe barrel and the luer-lock adapter. Grasp the needle shield with the other hand. To facilitate proper assembly, both **push and rotate** firmly.



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RESTYLANE PERLANE™

Restylane®

Natural beauty from within

Restylane Perlane™ – Instructions for Use

Composition

Hyaluronic acid, stabilized	20 mg/ml
Phosphate buffered saline	q.s.

Description

Restylane Perlane is a sterile, transparent gel of stabilized hyaluronic acid of non-animal origin. Restylane Perlane is supplied in a glass syringe with a luer-lock fitting. The contents of the syringe have been sterilized using moist heat. The product is for single use only. Disposable sterile needles are provided with each syringe. Information about the sterilization method and size of the needle is printed on its packaging. The number of units per package and the volume contained in each syringe is as stated on the outer package. A patient record label is a part of the syringe label. This label is to be attached to patient records to ensure traceability of the product.

Intended Use

Restylane Perlane is intended to be used for facial tissue augmentation. It is recommended to be used for shaping the contours of the face, the correction of folds and for lip enhancement. It should be injected into the deep layer of the dermis and/or the surface layer of the subcutis.

Mode of action

Restylane Perlane is a filler that adds volume to the tissue, thereby restoring the skin contours or enhancing the lips to the desired level of correction. The volume and the lifting capacity originate from the ability of hyaluronic acid to attract high amount of water, which is further increased by the stabilization process. Restylane Perlane will in time undergo isovolemic degradation, which means that the product maintains its volume even during degradation.

Warning

- Restylane Perlane is only intended for use as an intradermal and/or subcutaneous implant.
- Do not inject intravascularly. As for other injectable medical devices, inadvertent injection into blood vessels could potentially lead to vascular occlusion, ischemia and necrosis. Aspiration prior to injection is recommended.
- If blanching is observed, i.e. the overlying skin turns a whitish colour, the injection should be stopped at once and the area massaged until it returns to a normal colour.
- Do not use in patients with bleeding disorders or in patients who are taking thrombolytics or anticoagulants.
- Do not resterilize Restylane Perlane.
- Do not mix with other products prior to injection of the device.

Precautions

General considerations relevant to injectable medical devices

- 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 in close proximity to permanent implant or vulnerable structures such as nerves, vessels and other vital structures.
- Do not use where there is active disease, such as inflammation, infection or tumours, in or near the intended treatment site.
- 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 non-steroidal 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 package is damaged.

Specific considerations relevant to the use of Restylane Perlane

- Do not inject Restylane Perlane into an area where another injectable implant is present, except for other products from the Restylane range of products. Restylane Perlane should not be injected into an area where a non-injectable implant has been placed.
- The patient should minimize exposure of the treated area to excessive sun or extreme cold at least until any initial swelling and redness has resolved.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is performed after treatment with Restylane Perlane there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if Restylane Perlane is administered before the skin has healed completely after such a procedure.
- Restylane Perlane has not been tested in pregnant or breastfeeding women or in children.

Anticipated injection-related reactions

After the injection of Restylane Perlane, some common injection-related reactions might occur. These reactions include erythema, swelling, pain, itching, bruising or tenderness at the implant site. Typically resolution is spontaneous within a few days after injection into the skin and within a week after injection into the lips.

Adverse events

The most common adverse events reported post-marketing for the Restylane range of products are swelling, bruising, erythema, mass, pain and tenderness. Their reporting frequencies are about 1 in 10 000 to 1 in 20 000 treatments.

Less common adverse events with reporting frequencies about 1 in 50 000 treatments are infection, inflammatory reactions, discolouration, nodules and papules.

Rare cases of the following adverse events have been reported and these include pruritus, hypersensitivity reactions, reactivation of subclinical herpes infection in the face, acne-like lesions, granuloma, blisters, vesicles, induration, swelling of the face, urticaria, dermatitis, scarring or skin atrophy, short duration of effect, ischemia, injection site necrosis and telangiectasia.

Isolated rare cases of transient visual disturbance following inadvertent intra-arterial injection in the upper half of the face have been reported.

Symptoms of inflammation including a combination of redness, swelling, tenderness and induration at the implant site have been reported. These reactions may commence either shortly after injection or after a delay of 2-4 weeks. Infections should be excluded or treated if necessary. In pronounced cases a short course of oral corticosteroids may prove effective for implant site inflammation. For patients who have experienced clinically significant reactions, a decision for retreatment should take into consideration the cause and significance of previous reactions.

Post inflammatory pigmentation changes due to deposit of melanin have been observed in clinical studies in people with dark skin (Fitzpatrick Type IV-VI).

Adverse events must be reported to the local Q-Med representative or Restylane distributor.

Performance

In a controlled multicenter study with Restylane Perlane for the correction of nasolabial folds 75% of the subjects maintained a clinically significant improvement 6 months after treatment.

Assembly of needle to syringe

For safe use of Restylane Perlane it is important that the needle is properly assembled to the syringe. Improper assembly may result in separation of the needle and syringe during injection.

Use the thumb and forefinger to hold firmly around both the glass syringe barrel and the luer-lock adapter. Grasp the needle shield with the other hand. To facilitate proper assembly, both **push and rotate** firmly. See picture. The co-packed 29G TW needle is thin-walled and cannot be replaced by a regular 29G needle with a smaller inner diameter. In case a replacement needle is required a 27G needle should be used.

Treatment procedure

The correct injection technique is important for the final result of the treatment. Before the first treatment session, it is recommended to contact your local Q-Med representative or Restylane distributor for more information about injection techniques and training opportunities. Restylane Perlane is only intended to be administered by authorized personnel in accordance with local legislation. Before starting the treatment the patient shall be informed about the indications, expected result, precautions and potential adverse events. The patient's need for pain relief should be assessed. For optimal patient comfort, topical or local anaesthesia is recommended when shaping the contours of the face and correcting folds. For lip augmentation, anaesthesia through a nerve block can be used.

- Clean the treatment site thoroughly with a suitable antiseptic solution.
- To avoid needle breakage, do not attempt to bend the needle.
- Before injecting, remove the air by pressing the rod carefully until a small droplet is visible at the tip of the needle.
- Aspiration prior to injection is recommended.
- Inject slowly into the deep layer of the dermis and/or the surface layer of the subcutis while pulling the needle backwards using the needle provided. Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site.
- For each treatment site a maximum dosage of 2 ml per treatment session is recommended.
- Defects should be fully corrected, but not overcorrected, at each treatment session.
- The correction site should be massaged to conform to the contour of the surrounding tissues.
- If the skin of the patient is very loose, it is recommended that Restylane Perlane be injected on two or more separate occasions.
- After the first treatment, additional implantations of Restylane Perlane may be necessary to achieve the desired level of correction. Periodic follow-up injections help sustain the desired degree of correction.
- Depending on desired effect of contouring, degree of correction and individual patient need, it may in some cases be beneficial to combine different products from the Restylane range of products.

The syringe, the needle and any unused material must be discarded immediately after the treatment session and must not be reused due to risk for contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

Shelf life and storage

The expiry date is indicated on package. Store up to 25° C. Protect from freezing and sunlight.