

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. For facial areas with limited soft tissue support and soft tissue cover, e.g. the periorbital region, injection into the subcutaneous fatty tissue or supraperiosteal administration are recommended.

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

- 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.
- Knowledge of the anatomy of treatment site and special caution are required in order to avoid perforation or compression of vessels and other vulnerable structures.
- 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 edema formation are not suitable candidates for treatment of the lower periorbital region.
- 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 infection progressing into abscess formation, 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.

Isolated rare cases of ischemia/necrosis affecting the nose following injection treatment in patients who have had prior rhinoplasty 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. In case of unexplained inflammatory reactions, infections should be excluded and treated if necessary because inadequately treated infections may progress into complications such as abscess formation. Treatment using only oral corticosteroids without concurrent antibiotic treatment is not recommended. 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.

Needle

For safe use of Restylane Perlane it is important to use a sterile, appropriate needle or blunt cannula with a hub that fits the luer-lock of the syringe. Suitable disposable sterile 29G TW (thin-walled) needles are provided. In case a replacement needle is required a 27G needle should be used.

As an alternative, a blunt cannula can be used. The recommended size for a blunt cannula is 23-25G. The size and the length of the cannula will affect the force needed to extrude the gel. If a thinner cannula is used the resistance during injection may be too high resulting in an increased risk for leakage or separation of the cannula and syringe. The same considerations are applicable for needles.

Assembly of needle to syringe

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 (or hub if using cannula) with the other hand. To facilitate proper assembly, both **push and rotate** firmly. See picture. Strict aseptic technique must be followed.

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.

- Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be observed. Clean the treatment site thoroughly with a suitable antiseptic solution.
- To avoid 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.
- When using a needle, aspiration prior to injection is recommended. Inject slowly while pulling the needle backwards.
- Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site.
- As an alternative to the needle, a blunt cannula can be used. After preparation as described above, an entry point is made in the skin, e.g. with a sharp needle of appropriate size. Inject slowly. During injection, it is recommended to keep the side hole of the cannula facing downwards, away from the skin surface, to ensure that the flow of the gel is maintained at the correct depth in the dermis.

- Do not apply excessive pressure to the syringe at any time. Presence of scar tissue may impede advancement of the cannula/needle. If resistance is encountered the cannula/needle should be partially withdrawn and repositioned or fully withdrawn and checked for function.
- It is recommended to change needle/cannula for each new treatment 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 there is pronounced skin laxity, 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, disposable needle/blunt cannula 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.

Medicine Classification

Prescription Medicine

Manufactured by

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(Distributor on behalf of Q-Med (Sweden) Australia Pty Ltd)

Date of preparation

December 2010

Symbols on packaging



Do not use if package is damaged.



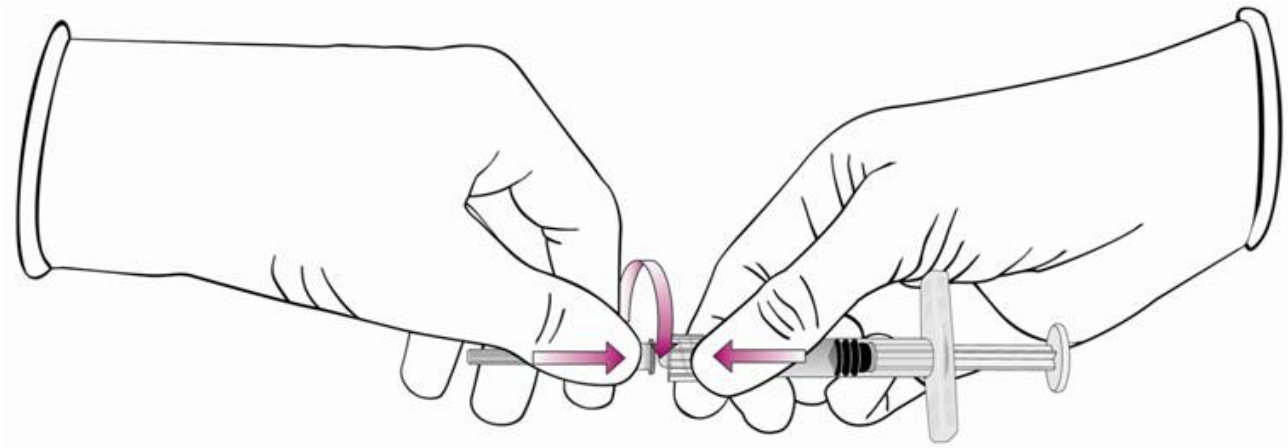
CE-marked according to MDD 93/42/EEC;
0344 is the Notified Body number for Restylane Perlane.



CE-marked according to MDD 93/42/EEC;
0197 is the Notified Body number for the co-packed needle(s).

Restylane Perlane and all other product names in the Restylane family, as well as NASHA are trademarks of Q-Med AB.

Picture included in the Instructions for Use



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