

Restylane® SubQ INSTRUCTIONS FOR USE

Composition:

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

Description

Restylane SubQ is a sterile, transparent gel of stabilized hyaluronic acid of non-animal origin. Restylane SubQ is supplied in a glass syringe with a luer-lock fitting. Each syringe is terminally moist heat sterilized in its packaging and packed in a paper carton. The product is for single use only. 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 SubQ is intended to be used for facial tissue augmentation. It is recommended to be used for shaping the contours of the face, e.g. more pronounced cheeks or chin. The depth of injection may vary from injection into the subcutaneous fatty tissue to supraperiosteal administration depending on the treatment site. Restylane SubQ shall only be injected by practitioners with expertise in the correction of volume defects in the facial area.

Mode of action

Restylane SubQ is a filler that adds volume to the tissue, thereby supporting the overlying (dermal) tissue to shape the contours of the face, 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 SubQ will in time undergo isovolemic degradation, which means that the product maintains its volume even during degradation.

Warning

- Restylane SubQ is only intended for subcutaneous and/or supraperiosteal administration.
- Do not inject intravascularly. As for other injectable medical devices, inadvertent injection into blood vessels could potentially lead to vascular occlusion, ischemia and necrosis. To ensure that the needle is not in a blood vessel, aspirate with the syringe before injection.

- Do not use in patients with bleeding disorders or in patients who are taking thrombolytics or anticoagulants.
- Do not resterilize Restylane SubQ.
- 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. If a sharp needle is used this is of particular importance.
- Special caution should be exercised when treating areas with limited collateral circulation, due to increased risk of ischemia.
- 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 SubQ

- Do not inject Restylane SubQ into an area where another injectable implant is present, except for other products from the Restylane range of products. Restylane SubQ 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.

- Based on clinical experience, adequate soft-tissue cover and soft-tissue support are important parameters to minimize the risk of local mobility and lumpiness. If any disturbing mobility or lumpiness should occur, correction can be attempted by aspiration of some of the implanted gel.
- Restylane SubQ has not been tested in pregnant or breastfeeding women or in children.

Anticipated injection-related reactions

After the injection of Restylane SubQ, 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 one to two weeks.

Adverse events

The incidence of adverse events from post marketing surveillance is less than 1%. These adverse events include inflammation, swelling, pain, tenderness, mass, induration, short duration of effect, erythema, local mobility and infection. Rare cases of the following adverse events have been reported and include infection progressing into abscess formation, bruising, papules, scar and telangiectasia. Inflammatory symptoms have been reported and may occur more than one month after implantation and may recur at the implant sites. 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.

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

Cannula/Needle

For safe use of Restylane SubQ it is important to use a sterile, appropriate cannula or needle with a hub that fits the luer-lock of the syringe. It is recommended to use a blunt cannula (with bullet tip) with a side exit, within the range of 16-21G. Sharp needles can be used by experienced physicians with thorough anatomical knowledge of the treatment site. The recommended sharp needle size is 21 G. If a thinner cannula/needle is used the resistance during injection may be too high resulting in an increased risk for leakage or separation of the needle/ cannula and syringe.

Assembly to syringe

It is important that the cannula/needle is properly assembled to the syringe. Improper assembly may result in separation of the cannula/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 hub of the blunt cannula (or needle shield if using needle) with the other hand. To facilitate proper assembly, both **push and rotate** firmly. See picture. Strict aseptic technique must be followed. Make sure that the hub is as tightly fixed to the luer-lock as possible. Different hubs may tighten at different levels.

Treatment procedure

The correct injection technique is important for the final result of the treatment. Different injection and administration techniques can be used. 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 SubQ is only intended to be administered by authorized personnel in accordance with local legislation. It should only be injected by practitioners with expertise in the correction of volume defects in the facial area.

Before the treatment, the patient's suitability for the treatment and the need for pain relief should be assessed. The patient should be informed about the indications, expected result, precautions and potential adverse events. To avoid a possible risk of product mobility the patient should be advised to avoid massaging the treatment site or applying pressure to the area for a few days following the injection.

- Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be observed. The treatment site should be cleaned with a suitable antiseptic solution and draped in an appropriate manner.
- Local anesthesia can be accomplished by injecting e.g. 0.5% lidocaine with epinephrine at the planned incision sites and at the site of planned implantation. Further anesthesia can be provided by regional nerve blocks. The use of anaesthetic containing a vasoconstrictive agent lowers the risk of accidental perforation of blood vessels.
- Restylane SubQ should be administered by injecting the material into the subcutaneous fatty tissue or supraperiostally. A too superficial injection may give rise to lumpiness.
- Before injecting remove the air by pressing the rod carefully until a small droplet is visible at the tip of the cannula/needle.
- If sharp needle is used, aspiration prior to injection is recommended.

- Do not apply excessive pressure to the syringe at any time. Presence of scar tissue may impede advancement of the cannula/needle. If such resistance is encountered the cannula/needle should be partially withdrawn and repositioned or fully withdrawn and checked for function.
- Inject Restylane SubQ while pulling the cannula/needle slowly backwards. Injection should stop well before the cannula/needle is pulled out from the skin to prevent material from leaking out from the injection site. The correction site should be gently massaged to conform to the contour of the surrounding tissues.
- It is recommended to use a new needle/blunt cannula for each new entry point.
- Only correct to 100% of the desired volume effect. Do not overcorrect.
- If the treated area is swollen directly after the injection, melting ice can be applied on the site for a short period.
- At each treatment session a maximum volume of 2 ml per treatment site is recommended.
- After the first treatment, additional implantations of Restylane SubQ 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 cannula/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.

Medicine Classification

Prescription Medicine

Manufactured by

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Name and Address of Sponsor

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58 Richard Pearse Drive,
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Auckland, New Zealand
(Distributor on behalf of Q-Med (Sweden) Australia Pty Ltd)

Date of preparation

December 2010

Symbols on packaging



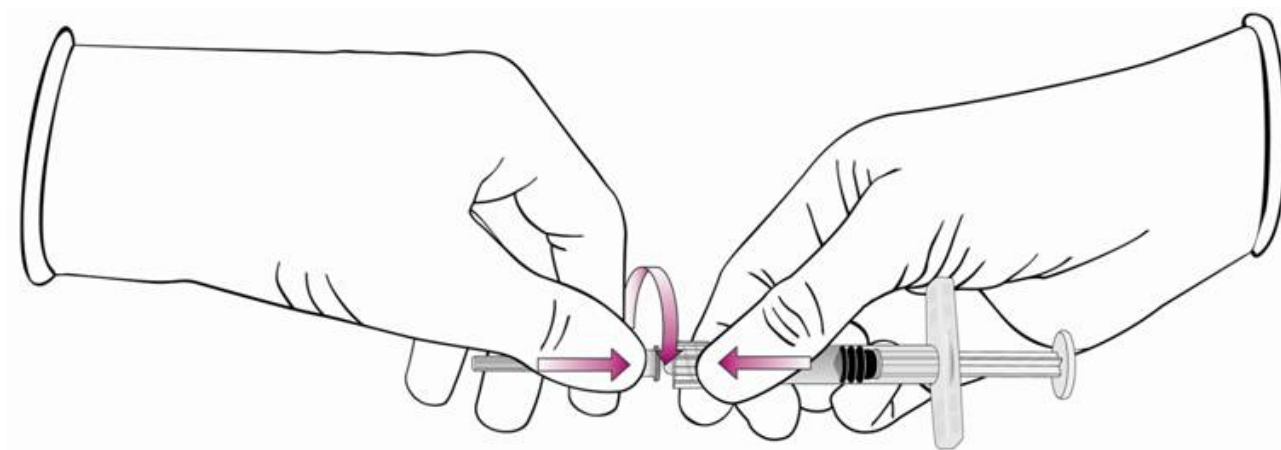
Do not use if package is damaged.



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

Restylane and 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 the hub of the blunt cannula (or needle shield if using needle) with the other hand. To facilitate proper assembly, both **push and rotate** firmly.