

## Restylane Vital™ INSTRUCTIONS FOR USE

### Composition

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

### Description

Restylane Vital is a sterile, transparent gel of stabilized hyaluronic acid of non-animal origin. Restylane Vital 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 Vital is intended to restore skin hydrobalance, improve skin structure and the elasticity of the skin. It should be injected in the dermal layer of the skin, preferably in the deeper part of dermis.

### Mode of action

Restylane Vital is naturally integrated into the skin where it helps to restore skin hydrobalance, improve skin structure and the elasticity of the skin. This is accomplished by the water associated with the stabilized hyaluronic acid in the gel. The unique characteristics of the gel help maintain the effect for a long period of time.

### Performance

In a clinical study with Restylane Vital, patients experienced significant improvement in dermal elasticity and skin morphology 6 months after initial treatment.

### Warning

- Restylane Vital is only intended for intradermal injections.
- Do not inject intravascularly. As for other injectable medical devices inadvertent injection into blood vessels could potentially lead to vascular occlusion ischemia and necrosis.
- 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 Vital.
- 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 Vital

- Do not inject Restylane Vital into an area where another injectable implant is present, except for other products from the Restylane® range of products. Restylane Vital 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 Vital there is a theoretical risk of eliciting an inflammatory reaction at the injection site. This also applies if Restylane Vital is administered before the skin has healed completely after such a procedure.
- Temporary palpable lumpiness has been noted in some patients. Do not inject too large volumes or too superficially, as the product then may cause intradermal lumps
- Restylane Vital has not been tested in pregnant or breastfeeding women or in children.

### **Anticipated injection-related reactions**

After the injection of Restylane Vital, some common injection-related reactions might occur. These reactions include erythema, swelling, pain, itching, bruising or tenderness at the injection site.

Typically resolution is spontaneous within a few days after injection.

### **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.

In rare cases intradermal lumps have been reported to remain for several months or periods over one year after the use of Restylane Vital.

Symptoms of inflammation including a combination of redness, swelling, tenderness and induration at the injection 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 injection 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.

## **Assembly of needle to syringe**

For safe use of Restylane Vital 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.

Hold firmly around the syringe barrel with the thumb and forefinger. To facilitate proper fastening of needle and syringe, please both **push and rotate** them firmly together. See picture.

## **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 Vital 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.

- Clean the treatment site thoroughly with a suitable antiseptic solution.
- To avoid needle breakage do not attempt to bend the needle
- Restylane Vital should be injected in the dermal layer of the skin, preferably in the deeper part of dermis.
- Before injecting, remove the air by pressing the rod carefully until a small droplet is visible at the tip of the needle.
- A too large volume or a too superficial injection may give bumps on the treatment site.
- Treated areas can be gently massaged immediately after the injection if any irregularities are noted.
- A treatment plan for Restylane Vital is recommended with three treatments 4 weeks apart. Generally it is recommended to repeat the treatment plan every 6 months, but results and patient preferences may vary.

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.

## **Medicine Classification**

Prescription Medicine

## **Manufactured by**

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## **Name and Address of Sponsor**

New Zealand

Pharmacy Retailing (NZ) t/a Healthcare Logistics

58 Richard Pearse Drive,

Airport Oaks

Auckland, New Zealand

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

## **Date of preparation**

February 2010

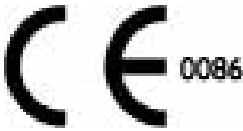
## **Symbols on packaging**



Do not use if package is damaged.



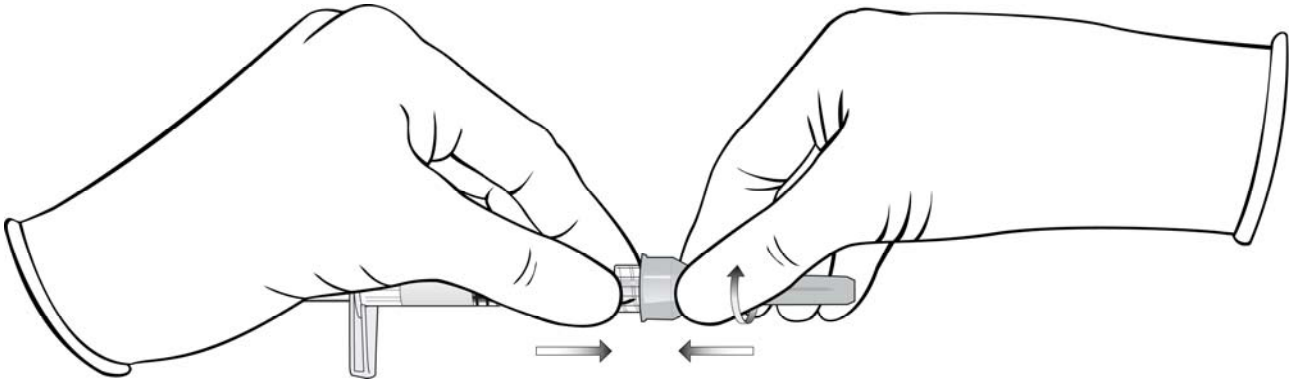
CE-marked according to MDD 93/42/EEC;  
0344 is the Notified Body number for Restylane Vital.



CE-marked according to MDD 93/42/EEC;  
0086 is the Notified Body number for the needle(s).

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

## Pictures included in the Instructions for Use



Hold firmly around the syringe barrel with the thumb and forefinger. To facilitate proper fastening of needle and syringe, please both push and rotate them firmly together.