RESTYLANE PERLANE INSTRUCTIONS FOR USE

GB

Formula

Contents

Hyaluronic acid, stabilized	20 mg/ml
Phys. sodium chloride solution, pH 7	q.s.

Description

RESTYLANE Perlane* is a clear, transparent and viscous gel supplied in a glass syringe together with one or more 27 G needles. The product is for single use only. RESTYLANE Perlane is a unique form of non-animal, stabilized hyaluronic acid (NASHA). Hyaluronic acid is a natural polysaccharide which occurs as an important structural element in the skin and in subcutaneous and connective tissues as well as in the synovial tissue and fluid. Hyaluronic acid belongs to a group of very few substances which are identical in all living organisms.

Mode of action

RESTYLANE Perlane acts by adding volume to the tissue, thereby shaping the contours of the face, correcting folds or enhancing the lips to the desired level of correction. RESTYLANE Perlane is naturally integrated into the tissue and will in time undergo isovolemic degradation.

Indication and usage

RESTYLANE Perlane is intended to be used for facial tissue augmentation. It is recommended that the product 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. With contour deformities the best results are obtained if the defect can be manually stretched to the point where it is eliminated. The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique. Markedly indurated defects may be difficult to correct. For lip enhancement both RESTYLANE Perlane and RESTYLANE* can be used. For the correction of cutaneous contour deformities such as wrinkles RESTYLANE is recommended. RESTYLANE Touch is recommended for the correction of thin superficial lines. Also combinations of RESTYLANE Perlane, RESTYLANE and RESTYLANE Touch can be used. Please consult the RESTYLANE and RESTYLANE Touch Instructions for Use for more information.

Warning

RESTYLANE Perlane is only intended for use as an intradermal and/or subcutaneous implant. Do not resterilize RESTYLANE Perlane. Do not inject intravascularly. Do not mix with other products.

Precautions

Normal precautions associated with intradermal and/or subcutaneous injections must be observed. Like any such procedure, the implantation of RESTYLANE Perlane is associated with an inherent risk of infection. RESTYLANE Perlane should not be used in or near anatomic sites where there is active skin disease, inflammation or related conditions. Do not use RESTYLANE Perlane together with any other injectable implant, except for RESTYLANE and RESTYLANE Touch. RESTYLANE Perlane should not be injected into an area where a permanent implant has been placed. RESTYLANE Perlane should not be used for patients with unattainable expectations.

The patient should be informed that he or she should not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold at least until the initial swelling and redness have resolved.

If laser treatment, chemical peeling or any other procedure based on active dermal response is considered 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. There is a potential risk with the procedure that the material could be inadvertently injected into blood vessels, which could lead to vascular occlusion in an end-artery with corresponding consequences. No such cases have been reported to date with RESTYLANE Perlane. RESTYLANE Perlane has not been tested in pregnant or lactating women or in children.

Anticipated side-effects

After the injection of RESTYLANE Perlane, some common injection-related reactions might occur. These reactions include erythema, swelling, pain, itching, discoloration 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. Additionally, temporary palpable lumpiness has been noted after the use of RESTYLANE Perlane in some patients. The composition of RESTYLANE Perlane is set to balance a normal tissue pressure. However, because the tissue pressure is sometimes disturbed to a higher value such as during oedema or to a lower value such as during dehydration, a small but significant change (swelling or shrinkage) may occur.

Adverse events

Reactions thought to be of a hypersensitivity nature have been reported in about 1 in every 10,000 treatments. These have consisted of swelling and induration at the implant site, sometimes with oedema in the surrounding tissues. Erythema, tenderness and rarely acneform papules may also occur. The reactions have started either shortly after injection or after a delay of 2-4 weeks and have generally been described as mild to moderate and self-limiting, with an average duration of 2 weeks. In pronounced cases a short course of oral corticosteroids may prove effective. In addition, rare cases (less than 1 in 15000 treatments) of granuloma formation, superficial necrosis and urticaria have been reported. Patients who have experienced this type of reaction should not be retreated with a RESTYLANE product.

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

Interactions

Treatment with RESTYLANE Perlane in combination with other drugs and devices has not been tested.

Assembly of needle to syringe

For safe use of RESTYLANE Perlane it is important that the needle is properly assembled. See pictures A and B.

A. Unscrew the tip cap of the syringe carefully.

B 1. Take a loose grip on the narrow part of the needle shield and mount the needle on the luer-lock by screwing until you feel somecounterpressure.

B 2. Take a new firm grip on the wider part of the needle shield. **Press and turn** it a further 90° (a quarter of a turn).

B 3. Pull off the needle shield.

Dosage and administration

Before the treatment, the patient's suitability for the treatment and the need for pain relief should be assessed. Normally, no anaesthesia is necessary when shaping the contours of the face and correcting folds. For lip augmentation, anaesthesia through a nerve block can be used. The patient should be informed about the indications, expected result, contraindications, precautions, warnings and potential adverse events. The treatment site should be cleaned with a suitable antiseptic solution. RESTYLANE Perlane is administered using a thin gauge needle (up to 27 G) by injecting the material into the deep layer of the dermis and/or the surface layer of the subcutis. If RESTYLANE Perlane is injected too deep or intramuscularly, the duration of the implant will be shorter because of a higher hyaluronic acid turnover rate. An injection too superficial may give blanching effects and bumps on the treatment site. 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. Before injecting, press the rod carefully until a small droplet is visible at the tip of the needle.

The injection technique with regard to the depth of injection and the administered quantity may vary. RESTYLANE Perlane should only be injected by practitioners who have experience of deep dermal and subcuteanous injections in the facial area. The linear threading technique can be used, but some physicians prefer a series of punctual injections or a combination of the two. During injection it is recommended that the eye of the needle should face upwards. Inject RESTYLANE Perlane while pulling the needle slowly backwards. Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site. In the treatment of lips, fullness and pouting of the lips can be obtained. Please consult your local Q-Med representative for details. Defects should be fully corrected, but not overcorrected, at each treatment session. If the skin of the patient is very loose, it is recommended that RESTYLANE Perlane be injected on two separate occasions. The correction site should be massaged to conform to the contour of the surrounding tissues. For each treatment site a maximum dosage of 2 ml per treatment session is recommended. If the treated area is swollen directly after the injection, melting ice can be applied on the site for a short period. 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.

Note! The correct injection technique is crucial for the final result of the treatment. RESTYLANE Perlane is only intended to be administered by authorized personnel in accordance with local legislation.

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.

The syringe, the needle and any unused material must be discarded directly after the treatment session.

How supplied

RESTYLANE Perlane is supplied in a glass syringe with a luer-lock fitting. One or more gamma irradiation sterilized needles, 27 G x 1/2", are packed together with each syringe. A patient record label is a part of the syringe label (see picture C). Remove it by pulling the flap marked with three small arrows (see picture D). This label is to be attached to patient records to ensure traceability of the product. The contents of the syringe are sterile. The number of units per package and the volume contained in each syringe is as stated on the outer package.

STERILE NEEDLE

- Follow national, local or institutional guidelines for use and disposal of medical sharp devices. Obtain prompt medical attention if injury occurs.
- To help avoid needle breakage, do not attempt to straighten a bent needle. Discard it and complete the procedure with a replacement needle.
- Do not reshield used needles. Recapping by hand is a hazardous practice and should be avoided.
- Discard unshielded needles in approved sharps collectors.

Shelf life and storage

As indicated on package. Store up to 25° C. Protect from freezing and sunlight.

Manufactured by

Q-Med AB, Seminariegatan 31, SE-752 28 Uppsala, Sweden
Phone +46 (0)18 474 90 00, Fax +46 (0)18 474 90 01
www.q-med.com, e-mail: info@q-med.com

IF THE PACKAGE IS DAMAGED, DO NOT USE

Symbols on packaging			
	Refer to instructions for use	LOT	Lot number
	For single use		Use by
STERILE	Sterile. The contents of the syringe have been sterilized by using moist heat.	STERILE R	Sterile. The needles have been sterilized by using irradiation.
CE	CE-marked according to MDD 93/42/EEC; 0344 is No of Notified Body for RESTYLANE Perlane. 0086 is No of Notified Body for the needles.		

References

Up-to-date product documentation is available at Q-Med in Sweden, at your local retailer or on www.restylane.com.