Restylane® Skinboosters™ Vital Light Lidocaine Instructions for Use

Composition

Hyaluronic acid, stabilized	12 mg/mL
Lidocaine hydrochloride	3 mg/mL
Phosphate buffered saline	q.s. ad 1 mL

Description

Restylane Skinboosters Vital Light Lidocaine is a sterile, transparent gel of stabilized hyaluronic acid of non-animal origin with the addition of 0.3% lidocaine hydrochloride. It is supplied in a glass syringe. The product has a built in dose-guide, SmartClick™ System, which when activated creates a clicking sound to indicate each injected dose. The 1 ml syringe gives approximately 100 doses. The contents of the syringe are sterilized using moist heat. The product is for single use only. Disposable 29G TW (thin-wall) needles, sterilized using ethylene oxide, are provided. An Implant Card for the patient is provided and includes a link to where an electronic Patient Information leaflet is located. To ensure traceability, patient record labels are included on the Implant Card and should be attached to patient records.

Intended use

This product 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. The addition of lidocaine provides increased overall treatment comfort.

Before the first treatment session, it is recommended to contact your local Galderma representative or Restylane distributor for more information about injection techniques and training opportunities. This product is only intended to be administered by authorized personnel in accordance with local legislation.

Mode of action

This product 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.

Contraindications

- Do not use in patients with a history of hypersensitivity to streptococcal proteins, as the product may contain trace amounts of such material.
- Do not use in patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- Do not use in patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics.

Warning

- Use at specific sites where there is active disease, such as inflammation (skin eruption such as cysts, pimples, rashes or hives), infection or tumours, in or near the intended treatment site should be avoided until the underlying process has been controlled.
- This product must not be injected intravascularly. Localized superficial necrosis and scarring may occur after injection in or near vessels, such as the nose and glabellar area. It is thought to result from the injury, obstruction, or compromise of blood vessels. Special caution should be taken if the patient has undergone a prior surgical procedure in the planned treatment area. Areas with limited collateral blood flow have an increased risk of ischemia.
- Unintentional introduction of soft tissue fillers into the vasculature in the face may lead to embolisation, occlusion of the vessels, ischemia, necrosis or infarction at the implant site or in the area supplied by the blood vessels affected. Rare but serious adverse events include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral haemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if any of the following symptoms occurs, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.
- Avoid use in patients with severe bleeding disorders.
- This product should not be mixed with other products prior to injection.

Precautions

- Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.
- This product should only be used by health care practitioners who have appropriate training, experience, and knowledge about the anatomy at and around the site of injection in order to minimize the risks of potential complications (perforation or compression of vessels, nerves and other vulnerable structures such as the eyes during treatments in the periorbital region).
- Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be followed.
- Avoid injecting into areas with, or in in close proximity to, prior implants other than hyaluronic acid, as this could aggravate latent adverse events or interfere with the aesthetic outcome of the treatment.
- Avoid large bolus injections or performing injections too superficially as this could lead to contour irregularities and palpable lumps.
- Injections in areas with limited soft tissue support, limited soft tissue cover or thin skin, (e.g., the periorbital area), may lead to contour irregularities and palpable lumps.
- Avoid injection in the lower periorbital region in patients with pre-existing pigmented dark lower eyelid circles, thin skin and pre-existing tendency toward oedema formation as this may be associated with more prominent discolouration and excessive swelling due to fluid build-up.
- Post inflammatory pigmentation changes may occur after dermal filler injections in people with dark skin (Fitzpatrick Type IV-VI).
- Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.
- This product should be used with caution in patients on immunosuppressive therapy.
- Patients who are using thrombolytics or anticoagulants or other 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.
- This product is packaged for single use. Do not resterilize.
- Do not use the product if package is opened or damaged, or if the expiry date or lot number is unreadable.
- Patients should avoid excessive sun, UV lamp exposure and extreme temperatures 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 this product there is a theoretical risk of eliciting an inflammatory reaction at the injection site. This also applies if the product is administered before the skin has healed completely after such a procedure.
- The safety for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine is used concurrently. High doses of lidocaine (more than 400 mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.
- Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g., certain anti-arrhythmics, since the systemic toxic effects can be additive.
- Lidocaine should be used with caution in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.

Adverse events

Anticipated injection-related reactions

Injection-related reactions (including bruising, erythema, itching, swelling, pain or tenderness at the implant site) might occur after treatment. Typically resolution is spontaneous within a few days after injection into the skin.

Post marketing adverse event reporting

The following post marketing adverse events have been reported from worldwide sources after treatments with the Restylane Skinboosters Vital light products (non-exhaustive list).

Swelling/oedema with immediate onset and onset up to several weeks after treatment, Papules/nodules, Mass/induration, Erythema, Pain/tenderness, Bruising/bleeding, Infection/abscess including pustule and cellulitis, Pruritus, Inflammation, Other injection site reactions and skin reactions including burning sensation, discomfort, dryness, irritation and warmth, Ischemia/necrosis including pallor and vascular occlusion, Device ineffective, Discolouration/pigmentation changes, Hypersensitivity, Rash, Neurological symptoms including hypoaesthesia and paraesthesia, Asymmetry/deformity, Granuloma/foreign body reaction, Urticaria, Acne, Dermatitis, Eye disorders such as ectropion and dry eye, Scarring, Blisters/vesicles, Encapsulation, Discharge/extravasation, Flare-up of herpes infection, Other dermatological events including skin exfoliation, skin hypertrophy and dry skin and Non-dermatological events including influenza-like symptoms such as pyrexia, headache and insomnia.

Vascular compromise may occur due to an inadvertent intravascular injection or as a result of vascular compression following implantation of any injectable product. This may manifest as blanching/pallor, discolouration, livedo reticularis, pain, necrosis, scab or ulceration at the implant site or in the area supplied by the blood vessels affected; or in rare cases, as ischemic events or infarction in other organs due to embolisation. Serious local ischemic events with possible scarring and rare cases of temporary or permanent vision impairment, blindness, reduced visual acuity, retinal artery occlusion, eye movement irregularities, cerebral ischemia or cerebral hemorrhage leading to stroke or pulmonary emboli, have been reported following the use of other injectable aesthetic products. Prompt medical attention and evaluation by an appropriate healthcare professional specialist is recommended should an intravascular injection occur.

In rare cases intradermal lumps have been reported to remain for several months or very rarely, longer than one year.

Symptoms of inflammation at the implant site commencing either shortly after injection or after a delay of up to several weeks have been reported. In case of unexplained inflammatory reactions infections should be excluded and treated if necessary since inadequately treated infections may progress into complications such as abscess formation. Treatment using only oral corticosteroids without concurrent antibiotic treatment is not recommended.

The prolonged use of any medication, e.g. corticosteroids or antibiotics in treatment of adverse events has to be carefully assessed, since this may carry a risk for the patient. In case of persistent or recurrent inflammatory symptoms, consider removal of the product by aspiration/drainage, extrusion or enzymatic degradation (use of hyaluronidase has been described in scientific publications; e.g. Jones DH, et al. Preventing and Treating Adverse Events of Injectable Fillers: Evidence-Based Recommendations from the American Society for Dermatologic Surgery Multidisciplinary Task Force. Dermatol Surg. 2021 Feb 1;47(2):214-226). Before any removal procedure is performed, the swelling may be reduced by using e.g. a short course of corticosteroids in order to more easily palpate any remaining product.

For patients who have experienced clinically significant reactions, a decision for retreatment should take into consideration the cause and significance of previous reactions.

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

For reporting of adverse events, contact your local Galderma representative or Restylane distributor for this product.

Performance

In a randomized, controlled study with Restylane Skinboosters Vital Light for the treatment of the face, dorsal hand, and décolletage, the blinded evaluator assessed more than 80% of subjects to have better skin quality on the treated side than on the untreated side throughout the 9-month follow-up. Also, in a small open-label extension study for the treatment of the face and neck, subjects experienced an aesthetic improvement on the treated side versus the untreated side.

Needle

Disposable sterile 29G TW (thin wall) needles are provided. Alternatively, a sterile blunt cannula 30G can be used. 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 (see pictures)

Improper assembly may result in separation of the needle and syringe during injection. A strict aseptic technique must be followed during the assembly procedure described below.

1. Put on sterile gloves.
2. Use your thumb and forefinger to hold firmly around both the syringe-barrel and the luer-lock adapter part (C) of the closure system.
3. With your other hand, take hold of the tip cap (A) at the end of the closure system and bend (do not rotate) until the cap disconnects and can be pulled off (tamper proof seal will be broken).
4. Do not touch the syringe tip (B) to keep it sterile.
5. Open the needle and grasp the needle shield.
6. Assure to hold both the syringe barrel and the luer-lock adapter (C).
7. To facilitate proper assembly, both push and rotate the needle firmly clockwise.
8. Make sure the needle is screwed on all the way so that the needle shield touches the luer lock adapter (C).
9. To remove the needle shield, hold the syringe and the luer lock adapter. With your other hand hold the needle shield and pull straight out. Do not rotate.
10. Activate the SmartClick System by pressing down the button on the finger grip (D) until it locks into place.

Treatment procedure

- The patient shall be informed about the indications, expected result, precautions and potential adverse events. The patient's need for additional pain relief should be assessed.
- Clean the treatment site thoroughly with a suitable antiseptic solution.
- To avoid breakage of the needle or cannula, do not attempt to bend it before or during treatment. If the needle gets bent, discard it and complete the procedure with a replacement needle.
- This product 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.
- If desired, the SmartClick System is activated by pressing down the button located on the finger grip (D) until it locks into place, see Picture.
- When the SmartClick System is switched on, again press the plunger rod carefully until the first click is heard to prime the system before use and to avoid a slightly larger volume of the first dose injected when the system is initially activated. The SmartClick System can be deactivated at any time by pushing the button in the finger grip upwards. It should be noted that it is not possible to perform an aspiration manoeuvre when the SmartClick system is activated.
- 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, 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 tissue depth.
- 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 for each new treatment site or following multiple punctures to avoid use of blunt needles and minimize the risk of infections.
- 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.
- If the treated area is swollen directly after the injection, an ice pack with adequate protective cloth can be applied on the site for a short period. Ice should be used with caution if the area is still numb from the anaesthetic to avoid thermal injury.
- Information regarding treatment can be filled in on the Implant Card and handed over to the patient.
- A treatment plan for this product with three treatments 4 weeks apart is recommended. Generally, a maintenance treatment is repeated every 6 months, but results and patient preferences may vary.

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.

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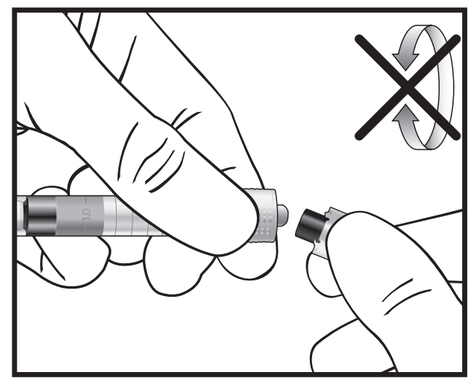
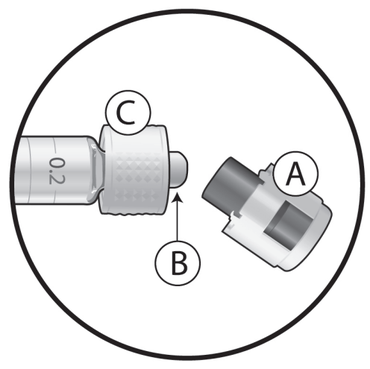
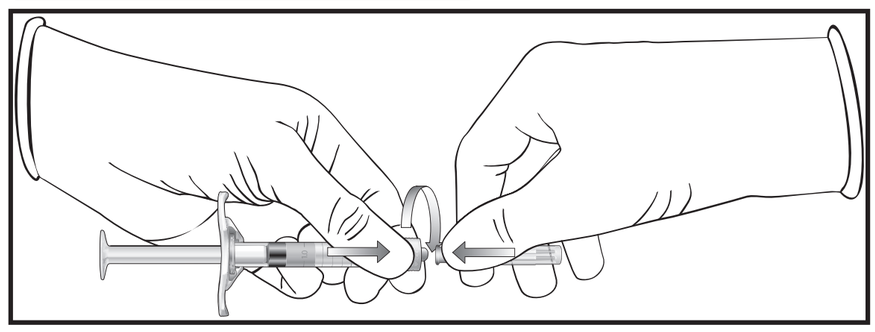
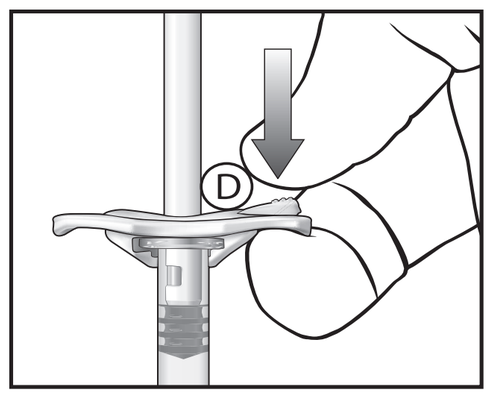
Symbols on packaging	
	Do not use if package is damaged.

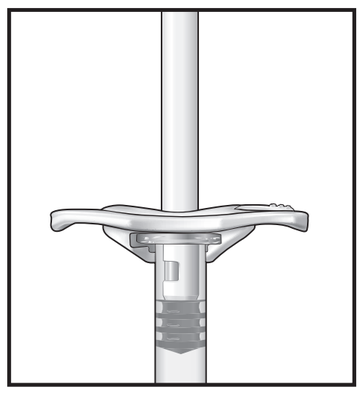
Manufacturer of the needles in the blister pack
Terumo Europe N.V.
Interleuvenlaan 40
3001 Leuven
Belgium











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