

Restylane® Skinboosters™ Vital Lidocaine - Instructions for Use

Composition
Hyaluronic acid, stabilized 20 mg/mL
Lidocaine hydrochloride 3 mg/mL
Phosphate buffered saline q.s.

Description
Restylane Skinboosters Vital 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, Smart Click 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-walled) needles, sterilized using ethylene oxide, are provided. To ensure traceability the patient record label (part of syringe label) should be attached to patient records.

Intended use
This product is intended to improve skin smoothness and appearance and the elasticity of the skin in the lower cheek/jawline in the face and dorsal hands. 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 improve skin smoothness and appearance 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 clinical studies with Restylane Skinboosters Vital, patients experienced significant improvement in dermal texture and skin morphology up to 6 months after initial treatment.

Contraindications
• Patients presenting with known hypersensitivity to hyaluronic acid filler, lidocaine or amide local anaesthetics.
• Patients with a history of hypersensitivity to streptococcal proteins, as the product may contain trace amounts of such material.
• Patients with bleeding disorders.
• Patients presenting with porphyria.
• Patients with known history of keloids.

Warning
• Do not inject intravascularly. Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction.
• Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures.
• Immediately stop the injection if a patient exhibits any of the following symptoms, 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.

Restylane® Skinboosters™ Vital Lidocaine - Mode d'emploi

Composition
Acide hyaluronique, stabilisé 20 mg/mL
Hydrochlorure de lidocaïne 3 mg/mL
Solution saline tamponnée au phosphate q.s.

Description
Restylane Skinboosters Vital Lidocaine est un gel stérile transparent d'acide hyaluronique stabilisé d'origine non animale, additionné d'hydrochlorure de lidocaïne à 0,3 %. Il est présenté dans une seringue de verre. Le produit est doté d'un système guide-dose intelligent intégré, appelé Smart Click, qui, une fois activé, émet un clic à chaque dose injectée. La seringue de 1 mL donne environ 100 doses. Le contenu de la seringue est stérilisé à la chaleur humide. Ce produit est réservé à un usage unique. Il est livré avec des aiguilles 29G à paroi mince jetables, stérilisées à l'oxyde d'éthylène. Par souci de traçabilité, l'étiquette d'enregistrement du patient (qui fait partie de l'étiquette de la seringue) doit être jointe au dossier du patient.

Usage prévu
Ce produit est destiné à lisser la peau du visage (dans la partie inférieure des joues et la région de la mâchoire) et de la face dorsale des mains et à en améliorer l'apparence et l'élasticité. Il injecte dans le derme, de préférence dans le derme profond. L'ajout de lidocaïne contribue à rendre l'ensemble du traitement moins inconfortable.

Il est recommandé de communiquer avec le représentant local de Galderma ou le distributeur de Restylane pour se renseigner sur les techniques d'injection et la formation offerte avant d'administrer le premier traitement. Le produit ne doit être administré que par du personnel autorisé conformément aux lois en vigueur.

Mode d'action
Ce produit s'intègre naturellement à la peau pour contribuer à la lisser et à en améliorer l'apparence et l'élasticité. Il agit grâce à l'association de l'eau à l'acide hyaluronique stabilisé dans le gel. Les caractéristiques uniques du gel aident à en prolonger l'effet.

Rendement
Lors d'études cliniques sur Restylane Skinboosters Vital, les patients ont observé une nette amélioration de l'élasticité du derme et de la morphologie de la peau jusqu'à six mois après le traitement initial.

Contre-indications
• Patients souffrant d'hypersensibilité connue aux produits de comblement à l'acide hyaluronique, à la lidocaïne ou aux anesthésiques locaux de type amide.
• Patients présentant des antécédents d'hypersensibilité aux protéines streptococciques, dont le produit peut contenir des traces.
• Patients souffrant de problèmes de coagulation.
• Patients souffrant de porphyrie.
• Patients présentant des antécédents de chéloïdes.

Mises en garde
• Ne pas injecter par voie intravasculaire. L'introduction de ce produit dans le système vasculaire peut causer une embolisation, une occlusion des vaisseaux, de l'ischémie ou un infarctus.
• On a signalé de rares cas d'événements indésirables graves associés à l'injection intravasculaire de produits de comblement des tissus mous du visage, notamment des troubles visuels temporaires ou permanents, la cécité, une ischémie ou une hémorragie cérébrale causant un accident vasculaire cérébral, une nécrose cutanée et des lésions des structures faciales sous-jacentes.
• Cesser immédiatement l'injection si le patient manifeste l'un ou l'autre des symptômes suivants, y compris des modifications de la vision, des signes d'accident vasculaire cérébral, un blanchiment de la peau ou une douleur inhabituelle durant ou peu après l'intervention.

• Défer use of the device where there is active disease such as inflammation, infection or tumours, in or near the intended treatment site until the disease has been controlled.
• Do not resterilize.
• Do not mix with other products prior to injection of the device.

Precautions
General considerations relevant to injectable medical devices
• In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection. Knowledge of the anatomy of treatment site and special caution are required in order to avoid perforation or compression of vessels, nerves and other vulnerable structures.
• 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.
• Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be observed.
• Use with caution in patients who are immunosuppressed.
• Special caution should be exercised when treating areas in close proximity to permanent implant.
• Localized ischaemia/necrosis or scarring may occur after injection in or near vessels. Special caution should be taken if the patient has undergone a prior surgical procedure in the planned treatment area.
• Special care should be exercised to avoid a too large or too superficial injection in treating facial areas with limited soft tissue support or soft tissue cover, to avoid formation of palpable lumps.

• Infection procedures can lead to reactivation of latent or subclinical herpes viral infections.
• Bruising and bleeding may occur at injection sites. The device should be used with caution in patients who have undergone therapy with thrombolytics, anticoagulants, or inhibitors of platelet aggregation, such as aspirin or non-steroidal anti-inflammatory drugs, in the preceding 2 weeks.
• Individuals with skin types (IVVI) may be prone to keloid formation. Ensure that the patient has no history of previous keloid formation.
• 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 this product
• Do not inject this product into an area where an implant of non hyaluronic acid has been placed.
• Patients should avoid 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 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.
• 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.
• This product has not been tested in pregnant or breastfeeding women or in children.
• Considerations should be given to the total dose of lidocaine administered. The maximum recommended 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 effect can be additive.
• Lidocaine should be used cautiously in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.
• Penitular injections of local anaesthetics carry a low risk of persistent ocular muscle dysfunction.

Adverse events
Anticipated injection-related reactions
Injection-related reactions might occur. These reactions include bruising, erythema, itching, swelling, pain or tenderness at the implant site. Typically resolution is spontaneous within a few days after injection into the skin.

Post marketing adverse event reporting
The frequency of post market adverse event reporting is calculated on the estimated number of treatments performed with the Restylane Skinboosters range of products.

I/10 000 – 1/50 000: Erythema, inflammation, pain/tenderness, papules/nodules, swelling
1/50 000 – 1/100 000: Bruising/induration
<1/100 000: Abscess, acne, atrophy/scarring, blisters, dermatitis, discolouration, granuloma, hypersensitivity infection, ischaemia/necrosis, mass, neurological symptoms such as paresthesia, pruritus, rash, reactivation of herpes infection, short duration of effect, telangiectasia, urticaria
Vascular compromise may occur due to an unintentional intravascular injection or as a result of vascular compression associated with implantation of any injectable product. This may manifest as blanching/discolouration such as a dusky or irregular appearance of the tissue, necrosis or ulceration at the implant site or in the area supplied by the blood vessels affected, or rarely as ischaemic events in other organs due to embolization. Rare but serious cases of stroke or cerebral ischaemia associated with temporary or permanent vision impairment, blindness, cerebral ischaemia or stroke have been reported following facial aesthetic treatments.

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

As for injectable dermal fillers, symptoms of inflammation at the implant site commencing either shortly after injection or after a delay of 2-4 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 (hyaluronidase injections). Before any removal procedure is performed, the swelling may be reduced by using e.g. NSAID for 2-7 days or a short course of corticosteroids for less than 7 days, 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.

Post-inflammatory pigmentation changes have been observed in clinical studies in people with dark skin (Fitzpatrick Type IV-VI).

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

Needle
Disposable sterile 29G TW 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
Use the thumb and forefinger to hold firmly around both the glass syringe and the luer-lock adapter. Grasp the needle shield (or hub if using cannula) with the other hand. To facilitate proper fastening, both push and rotate firmly, see figure 1. Strict aseptic technique must be followed. Improper assembly may result in separation of the needle and syringe during injection.

Treatment procedure
• The patient shall be informed about the indications, expected results, 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 or otherwise manipulate it before or during treatment.

• This product should be injected in the dermal layer of the skin, preferably in the deeper part of dermis.
• The Smart Click System is activated by pressing down the button located on the finger grip until it locks into place, see Figure 2.
• Before injecting, remove the air by pressing the rod carefully until a small droplet is visible at the tip of the needle. When the Smart Click System is switched on, press the plunger rod carefully until the first click is heard to prime the system before use.
• 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.
• Inject the product slowly and apply the least amount of pressure necessary.
• Do not apply excessive pressure to the syringe at any time. Presence of air bubbles may vary. The maximum volume 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.

• 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 this product with three treatments 4 weeks apart is recommended. Generally a maintenance treatment is repeated every 6 months, but results and patient response may vary. The maximum number of treatments of gel injected should not exceed 5 mL per treatment session and 20 mL per year and patient.

The syringe with finger grip and plunger rod, 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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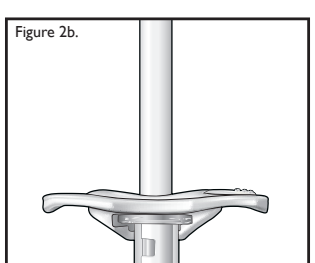
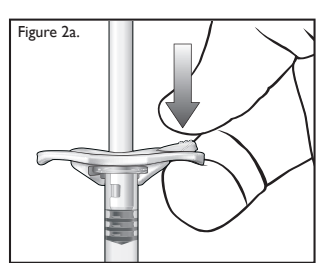
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Figure 1.
Use the thumb and forefinger to hold firmly around both the glass syringe barrel and the luer-lock adapter. Grasp the needle shield (or hub if using cannula) with the other hand. To facilitate proper assembly, both push and rotate firmly.

Figure 1.
Avec le pouce et l'index, entourer fermement le corps en verre de la seringue et le raccord Luer-Lock. Saisir le protecteur d'aiguille (ou l'embout s'il s'agit d'une canule) de l'autre main. Pour faciliter l'assemblage, pousser fermement et tourner à la fois.

Figure 2.
Activate the Smart Click System by pressing down the button on the finger grip (Figure 2a) until it locks into place (Figure 2b).

Figure 2.
Activer le système Smart Click en appuyant sur le bouton situé sur l'appui-doigt (Figure 2a) jusqu'à ce qu'il se bloque (Figure 2b).



GALDERMA

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Restylane® SKINBOOSTERS™ VITAL LIDOCAINE

Symbols on packaging Symboles sur l'emballage	
	Sterilized using steam or dry heat Stérilisé avec de la vapeur ou de la chaleur sèche
	Sterilized using ethylene oxide Stérilisé avec de l'oxyde d'éthylène
	Caution Attention
	Do not re-use Ne pas réutiliser
	Do not use if package is damaged and consult instructions for use Ne pas utiliser si l'emballage est endommagé et consulter les instructions d'utilisation
	Temperature limit Limite de température
	Keep away from sunlight Conserver à l'abri de la lumière du soleil
	Manufacturer Fabricant
	Catalogue number for the finished product Référence catalogue du produit fini
	Lot number Code de lot
	Use-by date Date limite d'utilisation
	Do not resterilize Ne pas restériliser
	Single sterile barrier system Système de barrière stérile unique
	Date of manufacture Date de fabrication
	CE-mark for Terumo Marquage CE de Terumo
	Medical Device Dispositif médical
	Non-pyrogenic Non pyrogène
	Forest Stewardship Council