Patient information - Restylane® Skinboosters™ Vital Light Lidocaine

Manufacturer name
Q-Med AB
Seminariegatan 21
SE-752 28 Uppsala
Sweden
www.galderma.com

Sponsor:
Galderma Australia Pty Ltd
Level 18, 1 Denison Street
North Sydney NSW 2060
Phone 1800 800 765

Health authority name, address and website:
Therapeutic Goods Administration PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Glossary
Anaesthetic – a medication (or "treatment") that reduces pain.
BDDE – the ingredient used to crosslink the **HA**.
Crosslinked – a process in which HA chains are connected to form a network.
Hyaluronic acid (HA) – a naturally occurring sugar, found in the body that gives the skin moisture, volume and elasticity.
Lidocaine – a commonly used local **anaesthetic** to numb the skin, see "**anaesthetic**".
Topical – a cream or ointment applied to the top of the skin, affecting only the area to which it is applied.

What is Restylane Skinboosters Vital Light Lidocaine?

Restylane Skinboosters Vital Light Lidocaine is a sterile, clear injectable gel composed of hyaluronic acid (HA), a natural substance that already exists in the body. Once injected to the skin the product gradually breaks down and disappears over time. The HA in the product is crosslinked with BDDE**,** an ingredient that helps form a network of HA to provide a gel that lasts longer when injected into the skin. The product is non-animal-based and free from animal protein. The product contains lidocaine, a medication to reduce the discomfort associated with the injection treatment. The gel is supplied in a glass syringe.

How does the product work?

Restylane Skinboosters Vital Light Lidocaine helps to improve skin hydration, skin elasticity and smoothness of the skin. This is accomplished by the ability of crosslinked sodium hyaluronate to bind water. The addition of lidocaine provides a pain-relieving effect during treatment.

How often should I do the treatment?

An initial treatment cycle for this product with 3 treatment sessions 4 weeks apart is recommended. A maintenance treatment can be repeated every 6 months depending on your skin situation and preferences.

Users:

- The product shall only be used in persons over 18 years of age
- You should only be given the product by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law

Are there any reasons why I should not use Restylane Skinboosters Vital Light Lidocaine?

To ensure a safe procedure, your healthcare professional will talk to you about your medical history to determine if you are an appropriate candidate for treatment. Treatment with the product may result in an allergic reaction. You should not use the product if:

- You are allergic to streptococcal proteins from the bacteria which are used to make the HA in the product (bacterial proteins).
- You have severe allergies with a history of severe reactions (anaphylaxis) or multiple severe allergies.
- You are allergic to the anaesthetic lidocaine.

If you are not sure about your medical history concerning these allergies, please discuss further with your healthcare professional.

Are there other warnings or precautions that I should discuss with my healthcare professional?

Warnings

Before having the injection, tell your healthcare professional if:

- You have areas with skin sores, pimples, rashes, hives, cysts, or infections. The treatment should be postponed until healing is complete as this could delay healing or make your skin problems worse.

- You are prone to bleeding or have been diagnosed with a bleeding disorder.

One of the risks with using this product is unintentional injection into a blood vessel. The risk of this happening is very small, but if it does happen, the complications can be serious, and may be permanent. These complications, can include temporary scabs, permanent scarring of the skin, temporary or permanent vision changes, blindness or stroke.

After having the injection, seek immediate medical attention if:

- You have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), signs of a lung emboli (including sudden shortness of breath and sharp chest pains that get worse if you exert yourself or take a deep breath), white appearance of the skin, or unusual pain during or shortly after treatment.

Precautions

There are several other important precautions to discuss with your healthcare professional to ensure a satisfactory result and to avoid any complications. Please be sure to discuss the following with your healthcare professional if:

- You are breastfeeding or pregnant. The safety of Restylane Vital Lidocaine for use during pregnancy, or in women who are breastfeeding, has not been studied.

- You are on any medications to decrease your body's immune response (immunosuppressive therapy).

- You are taking any medication that can thin your blood or prolong bleeding, such as aspirin and warfarin. As with any injection procedure this may have a higher risk of severe bleeding or bruising.

- You have any skin colour (pigmentation) disorder or have dark skin. This might increase your risk of developing skin discoloration after treatment.

- You have a history of herpes infection; this could be reactivated as a result of an injection.

- You have prior implants, other than hyaluronic acid, in the intended treatment location in your face, as this could increase the risk of side effects or interfere with the aesthetic outcome of the treatment.

- You recently had skin therapies such as laser treatment, mechanical or chemical peels. This may lead to increased risk of side effects such as redness, swelling, heat or pain of the skin.

- You have a dental block or use topical lidocaine at the same time as the Restylane Skinboosters Vital Light Lidocaine treatment. High doses of lidocaine could cause a toxic reaction.

If you have any additional questions about any topic in this section, please discuss further with your health care professional.

Which benefit can I expect from the use of Restylane Skinboosters Vital Light Lidocaine
In one clinical study on Restylane Skinboosters Vital Light for the treatment of the face, back of the hands, 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 study for the treatment of the face and neck, subjects experienced an aesthetic improvement on the treated side compared to the untreated side.

All residual risks and potential undesirable side-effects listed

Local skin reactions such as bruising, redness (erythema), itching (pruritus), swelling, pain or tenderness are expected and commonly occur at the treatment location after the injection procedure. Usually, these reactions do not need any treatment and will go away by themselves within a few days after the injection.

Spontaneously reported side effects from healthcare professionals and customers using the product included:

- Temporary swelling (oedema) with immediate onset or delayed onset, up to several weeks after treatment
- Lumps/bumps (papules/nodules)
- Mass formation/hardening (induration)
- Redness (erythema)
- Pain/tenderness
- Bruising/bleeding
- Infection/pockets of pus (abscess)
- Itching (pruritus)
- Inflammation
- Skin reactions at the injection location including burning sensation, irritation, discomfort, dryness and warmth
- Restricted blood flow/tissue death (ischemia/necrosis) including paleness of skin (pallor) and blockage of a blood vessel (vascular occlusion)
- Short duration of effect (device ineffective)
- Skin discolouration/pigmentation changes
- Allergic reaction (hypersensitivity)/rapid swelling (angioedema)
- Rash
- Tingling sensation (paraesthesia)/reduced sense of touch (hyperesthesia)
- Uneven appearance of the skin (asymmetry/deformity)
- Small area of inflammation in tissue (granuloma)
- Hives (urticaria)
- Acne
- Skin irritation (dermatitis)
- Eye disorders including eyelid turns outward (ectropion) and dry eye
- Scarring
- Blisters
- Encapsulation

- Leakage from implant site (discharge)
- Symptoms of reactivation of herpes infection
- Other side effects not associated with the treatment location including headache, and influenza like symptoms such as fever, and insomnia
- Other local side effects including skin exfoliation, skin thickness (hypertrophy) and dry skin

The healthcare professional performing the treatment may accidentally inject the product into a blood vessel. This may cause restricted blood flow (ischemia) and tissue death (skin necrosis) at the injection site, surrounding skin areas or in other areas further away such as the eyes or brain. The risk for this is very small, but if it does happen, the complications can be serious, and may be permanent. These complications, can include skin discoloration, temporary scabs, formation of wounds and scarring of the skin, temporary or permanent vision changes blindness, eye movement irregularities, lung damage or stroke.

Delayed inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed 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.

When and how to report undesirable side effects

If you have any questions concerning possible side effects, please discuss further with your healthcare professional. You should always tell your healthcare professional if you experience anything unusual at the site of treatment.

Any serious incident that occurs in relation to the device should also be reported to the Australian Government Therapeutic Goods Administration through their website at:
www.tga.gov.au

After procedure information

What should I do after receiving treatment?

- For the first 24 hours, you should avoid or minimize hard (strenuous) exercise. You should also avoid or minimize exposure to extensive sun UV lamps and extreme temperatures until any swelling and redness has resolved. Exposure to any of these may cause the area where you were treated to temporarily become red, swell and/or itch. If you experience any of these problems, an ice pack can be applied for a short period for relief.
- Avoid touching, shaving or excessive washing of the treated area and do not apply any creams or cosmetics in the treated area before the skin has healed completely in order to prevent infections or other local skin reactions.

When should I call my doctor? What should I call my doctor about after the treatment?

You should call your doctor immediately if you have:

- Changes in your vision.
- Signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion).

- Signs of a lung emboli (including sudden shortness of breath and sharp chest pains that get worse if you exert yourself or take a deep breath).
- White appearance of the skin.
- Unusual pain during or shortly after treatment.

Be sure to call your doctor if you have:

- Persistent injection site reactions beyond 14 days, as most side effects such as bruising, swelling, pain, tenderness, redness, and itching will usually go away by itself within one to two weeks.
- Blisters or skin sores that recur, which may signal the presence of a herpes infection.
- Any signs of infection such as fever, redness that spreads to surrounding areas, drainage, increasing tenderness or increasing pain that does not go away. If you develop an infection you may need antibiotics. If it gets worse, you may need other treatments, such as surgery.
- Significant pain away from the injection site.

Article number: 90-33189-01

Revision date: March 2025