Patient information - Restylane® Volyme™

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

Sponsor name, address:
Galderma Australia Pty Ltd
Suite 4, 13B Narabang Way
Belrose NSW 2085
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 "**anesthetic**".
Topical – a cream or ointment applied to the top of the skin, affecting only the area to which it is applied.

Product description

What is Restylane Volyme?
Restylane Volyme is a sterile, clear injectable gel composed of hyaluronic acid (HA), a natural substance that already exists the body. Once injected into 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 chains 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 plastic syringe.

How does the product work?
Restylane Volyme is a filler that is injected into the facial skin to add volume to the tissue. It is recommended to be used to provide facial volume such as in cheeks and chin.

The products ability to give volume to the tissue comes from the ability of HA to bind water.

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 Volyme?

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 or 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.

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, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

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), 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 Volyme 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 have any skin colour (pigmentation) disorders or have dark skin. This might increase your risk of developing skin discolouration after treatment.

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

- You have permanent implants in the intended treatment location in your face or other prior implants, 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 filler 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 healthcare professional.

How long does the product last?

- In a study where several areas in the face were treated with the product, all subjects had improved restoration of facial volume 3 weeks after the last injection. The effect was sustained 18 months after the last treatment in more than two-thirds of the subjects.

- In another clinical study where several areas in the face were treated with various Restylane products, a majority of subjects were reported with maintained cheek volume up to at least 6 months after treatment with Restylane Volyme.

All residual risks and potential undesirable side-effects listed

As with any medical procedure, there are risks involved with the use of injectable fillers.

Local skin reactions such as bruising, pain or tenderness, swelling, redness (erythema) and itching (pruritus), 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 one week 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
- Mass formation/hardening (induration)
- Pain/tenderness
- Lumps/bumps (papules/nodules)
- Redness (erythema)
- Short duration of effect (device ineffective)
- Inflammation
- Infection/pockets of pus (abscess)
- Bruising/bleeding
- Allergic reaction (hypersensitivity)/rapid swelling (angioedema) including extreme allergic reaction (anaphylactic shock)
- Restricted blood flow (ischemia/necrosis) including paleness of skin (pallor)
- Facial nerve paralysis, reduced sense of touch (hypoaesthesia), tingling sensation (paraesthesia)
- Implanted gel moving from site of injection (device dislocation)
- Other injection site reactions and skin reactions including burning sensation and warmth
- Eye disorders including eye pain, eyelid swelling (oedema), eyelid drooping (eyelid ptosis) and dry eyes
- Small area of inflammation in tissue (granuloma)
- Skin discolouration
- Uneven appearance of the skin (asymmetry/deformity)
- Itching (pruritus)
- Symptoms of reactivation of herpes infection
- Rash
- Blisters
- Scarring
- Acne
- Skin irritation (dermatitis)
- Encapsulation
- Hives (urticaria)
- Other side effects not associated with the treatment location including chills, dizziness, feeling hot, headache, influenza like illness, migraine and feeling faint (presyncope)
- Other local side effects such as dry lips (chapped lips)

The healthcare professional performing the treatment may accidentally inject the product into a blood vessel, which can cause injury to the blood supply. The risk for this is very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include death of tissue (skin necrosis) with temporary scabs, or permanent scarring of the skin, and in rare cases temporary or permanent vision changes, including blindness, or stroke.

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.

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 or shaving the treated area and not to 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).
- White appearance of the skin.
- Unusual pain during or shortly after treatment.

Be sure to call your doctor if you have:

- Persistent skin reactions at the treatment location beyond 14 days after the injection, as any side effects such as bruising, swelling, pain, tenderness, redness, and itching will usually go away by itself within one week.
- Blisters or skin sores that recur, which may signal the presence of a herpes infection.
- Any signs of infection such as fever, or redness that spreads to surrounding areas of your skin, drainage of pus from the injection location, increasing tenderness or increasing pain from the treatment location 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 treatment location.

Article Number: 90-87121-01
Revised: October 2022