**Patient information - Restylane® Lidocaine**

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## 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.

## Product description

### What is Restylane Lidocaine?

Restylane Lidocaine is a sterile, clear injectable gel composed of hyaluronic acid (HA), a natural substance that already exists in 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. Restylane Lidocaine 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 Restylane Lidocaine work?

Restylane Lidocaine is a filler that is injected into the skin to add volume to the tissue. The product is indicated for, smooth away wrinkles and for enhancement of the lip.

The products ability to give volume to the tissue and smooth out wrinkles 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 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 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 chances of this happening are 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 Lidocaine for use during pregnancy, or in women who are breastfeeding, has not been studied.

- You or 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 discoloration 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 health care professional.

**How long does Restylane Lidocaine last?**

- In a clinical study where wrinkles running from the nose to the corner of the mouth were corrected, 74% of subjects were still improved 6 months after treatment as the filler gradually disappears from the body.

- In a clinical study, subjects were treated on both sides of the face in the wrinkles running from the nose to the corner of the month. One of the folds had a retreatment after 4,5 month and the other fold was retreated after 9 months. At 18 months, 97% of the subjects were still improved with little or no difference between the 4.5 or 9 months re-treatment schedule. The study was extended to a 36 month follow up and included a retreatment at 18 months, if required. Improvement was obtained in 94-100% of subjects in the follow up period from 24 to 36 months.

- In another clinical study where wrinkles running from the nose to the corner of the mouth were corrected, 74% of subjects were still improved 18 months after initial treatment, including a re-treatment at 9 months.

**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, redness, itching, 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 one week after the injection.

Spontaneously reported side effects from health care professionals and customers using Restylane Lidocaine include:

- Temporary swelling (oedema) with immediate onset or delayed onset, up to several weeks after treatment
- Mass formation/hardening (induration)
- Short duration of effect (device ineffective)
- Redness (erythema)
- Pain/tenderness
- Bruising/bleeding
- Uneven appearance of the skin (asymmetry/deformity)
- Lumps and bumps (papules/nodules)
- Infection/pockets of pus (abscess)
- Skin discolouration
- Restricted blood flow (ischemia/necrosis) including purplish discolouration (livedo reticularis), paleness of skin (pallor), blockage of a blood vessel (vascular occlusion)
- Skin reactions at the injection location including burning sensation, exfoliation, irritation, discomfort, dryness and warmth
- Inflammation
- Allergic reaction (hypersensitivity)/rapid swelling (angioedema)
- Eye disorders including dry eyes, eye irritation, eye pain, eye swelling, eyelid drooping (eyelid ptosis), increased tear flow, (increased lacrimation), blurred vision and visual disturbance such as reduced vision and blindness
- Facial nerv paralysis, reduced sense of touch (hypoaesthesia), tingling sensation (paraesthesia)
- Itching (pruritus)
- Leakage from implant site (discharge)
- Scarring
- Implanted gel moving from site of injection (device dislocation)
- Small area of inflammation in tissue (granuloma)
- Symptoms of reactivation of herpes infection
- Rash
- Blisters
- Dilated small blood vessels (telangiectasia)
- Hives (urticaria)

- Skin irritation (dermatitis)
- Muscle twitching and muscular weakness
- Encapsulation
- Other side effects not associated with the treatment location including anxiety, joint pain (arthralgia), weakness (asthenia), depression, dizziness, difficulty swallowing (dysphagia), shortness of breath (dyspnoea), fatigue, headache, feeling sick (malaise), fever (pyrexia), influenza like illness, sinusitis, trouble falling asleep (insomnia) and nausea
- Other local side effects including hair loss (alopecia) and skin wrinkling

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 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 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.
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 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 effect 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, 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.

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