

Restylane Kysse

Patient Brochure

About Restylane® Kysse

Before beginning your treatments, please review this important information.

1. GLOSSARY

Anesthetic – a medication (or “treatment”) that reduces pain

Dermal filler – a material that is injected underneath the skin to smooth a wrinkle or restore volume to an area of skin

Hyaluronic acid (HA) – a naturally occurring sugar, found in the body that gives the skin moisture, volume, and elasticity.

Hyaluronidase – an enzyme that breaks down hyaluronic acid

Lidocaine – a commonly used local anesthetic to numb the skin, see “anesthetic”

XpresHAN Technology™ –the unique manufacturing process used to make *Restylane Kysse* hyaluronic acid injectable gel

BDDE – the ingredient used to crosslink the **HA**.

Perioral Lines – the wrinkles in the skin around the mouth and lips.

Pigmentation disorder – A disorder that results in a change in skin color

Topical –a cream or ointment applied to the top of the skin, affecting only the area to which it is applied

Touch-up – an additional injection of dermal filler that is usually given a short time after the initial injection. Some patients may require a touch-up treatment to achieve the desired result

Injection site responses – side effects from treatment

Crosslinked – a process in which **HA** chains are connected together to form a network.

2. PRODUCT DESCRIPTION

What is Restylane Kysse?

Restylane Kysse is a clear injectable gel composed of **hyaluronic acid (HA)**. **HA** is a naturally occurring sugar, found in the human body.

Restylane Kysse is **crosslinked** with **BDDE**, an ingredient that helps form a network of **HA** to provide a gel filler that lasts longer. **HA** fillers, including *Restylane Kysse*, contains **HA** that has been modified to last longer in the body than the naturally occurring **HA**. *Restylane Kysse* contains 0.3 % lidocaine to reduce pain during injection.

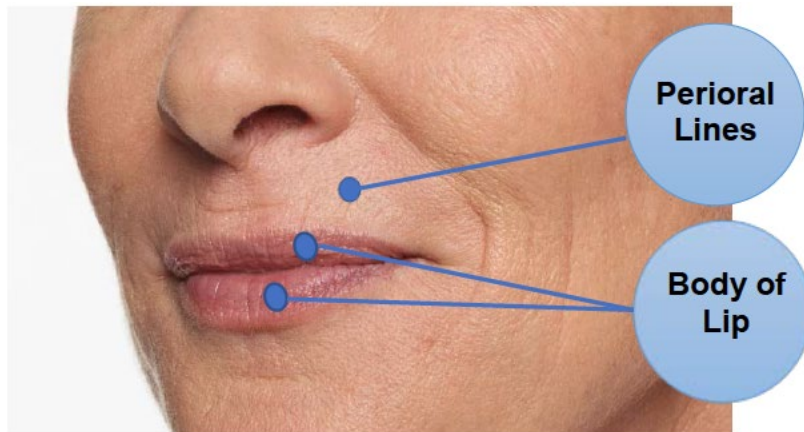
INDICATIONS FOR USE

What is *Restylane Kysse* for?

Restylane Kysse is injected into the lips and the lines around the upper lip to temporarily add fullness to the lips and help smooth the wrinkles around the upper lip (perioral lines) in patients over the age of 21.

How is *Restylane Kysse* used?

Restylane Kysse is injected with an ultrafine needle into your lips to add fullness. It can also be injected into the skin above your lips to help smooth the wrinkles around your upper lip (perioral lines). The picture below shows the treatment areas for *Restylane Kysse*.



3. CONTRAINDICATIONS

Are there any reasons why I should not receive *Restylane Kysse*?

Your doctor will ask about your medical history to determine if *Restylane Kysse* is right for you. Patients with any of these conditions should not use *Restylane Kysse*:

- Highly allergic (for example: a history of severe allergic reaction or multiple severe allergies). Use may result in an allergic reaction.
- If you have previous experience with allergic reactions to HA fillers. Use may result in an allergic reaction.
- Allergic to anesthetics, such as lidocaine. Use may result in an allergic reaction.

4. PRECAUTIONS

What precautions should my doctor discuss with me?

- The use of Restylane Kysse where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of Restylane Kysse where these are present could delay healing or make your skin problems worse.
- As with any injection procedure, you may have a higher risk of bruising or bleeding at the injection site if you have a bleeding disorder.
- Tell your doctor if you are using St. John's Wort, high doses of Vitamin E supplements, aspirin, and other NSAIDs, such as ibuprofen, because these may increase bruising or bleeding at the injection site.
- Tell your doctor if you are planning other skin therapies such as laser, mechanical or chemical peeling, microneedling and hair removal after treatment. The use of Restylane Kysse with these skin therapies may lead to other side effects such as inflammation.
- After treatment with Restylane Kysse, you should minimize exposure to the sun and avoid being in the heat and cold until any redness or swelling has disappeared. Exposure to any of these may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are pregnant or breastfeeding. The safety and effectiveness of Restylane Kysse has not been established in pregnant women or nursing mothers.
- Tell your doctor if you are on a therapy to decrease the body's immune response. Treatment may result in an increased risk of infection.
- Tell your doctor if you have a history of thick, hard scars (excessive scarring). The safety and effectiveness of Restylane Kysse in patients with a history of thick, hard scars has not been studied and may result in additional scarring.

5. CLINICAL STUDIES

How was *Restylane Kysse* Studied?

Restylane Kysse was tested, to ensure that it worked properly (effective) and was safe to use, in a clinical study before it was approved for use in all subjects. This study included 261 women, 9 men, and were from various ethnic groups with multiple skin tones (pale to dark skin). Each of these subjects expressed desire to augment their lips. Subjects could also treat the lines around the upper lip.

The study was created to compare two different dermal filler gel products. It was conducted by 14 different doctors in 14 different locations across the United States.

Subjects who participated in the study received an initial treatment with *Restylane Kysse* or another similar dermal filler gel. The selection of product was randomly assigned to each subject so that 185 subjects received *Restylane Kysse* and 88 subjects received the comparator product. Touch-up injections were given as needed after 4 weeks with the same product as used at the initial treatment. Each subject was monitored for 12 months following the procedure to measure the effect of treatment. For each subject, the amount of product used was based on their individual need.

In order to objectively measure improvements in lip augmentation over 12 months, each subject was evaluated by a doctor other than the one who had performed the treatment. Subjects also evaluated

themselves. To measure side effects following the procedure, each subject kept a diary for 30 days to record side effects. These were then shared with the doctors.

After 12 months, all subjects could receive an optional treatment with *Restylane Kysse*, independent on what product they had been treated with initially. Subjects that received re-treatment were monitored for another 4 weeks for the effect and safety of repeat treatments.

6. BENEFITS

What will *Restylane Kysse* do for me?

Restylane Kysse will temporarily add volume to the lips and help smooth the wrinkles above your mouth.

Restylane Kysse was studied in many subjects like yourself to determine if it was effective and to ensure that it is safe for use.

The study doctors reported:

- 77% (129/168) of subjects had at least a 1-point improvement in lip fullness 6 months after treatment
- 60% (101/169) of subjects had at least a 1-point improvement in lip fullness 12 months after treatment

The subjects reported:

- 88% (148/169) rated an improvement in the appearance 6 months after treatment
- 78% (132/169) rated an improvement in the appearance 12 months after treatment

7. RISKS

What side effects were seen in the clinical study?

In the study of *Restylane Kysse*, most side effects were mild or moderate in nature and their duration was short lasting (7 days or less). The most common side effects included, but was not limited to, temporary **injection site responses** such as:

- redness,
- pain/tenderness,
- firmness,
- swelling,
- lumps/bumps,
- bruising,
- itching,
- discoloration.

Other potential risks may arise from an injection of a dermal filler gel such as *Restylane Kysse* including the following:

- Infection - Any time a dermal filler gel like *Restylane Kysse* is injected into facial skin there is risk of infection, which could appear as small, swollen or red bumps. These are called inflammatory papules. These infections are rare, however you should talk to your doctor about further treatment if you see any of these signs or symptoms.
- Scarring - While it is very rare, scarring may occur with an injection procedure. When *Restylane Kysse* was studied, there was no excessive scarring (a condition called keloids) observed in patients who received *Restylane Kysse*.
- Change in skin tone - If you are African American, you may have a higher risk of darkening of the skin tone (hyperpigmentation) in the treated area. This may take several weeks to disappear. When *Restylane Kysse* was studied, this change in skin tone did not occur in patients who received *Restylane Kysse*.
- Cold sores - If you have had cold sores in the past, there is a risk that they will return after your procedure with *Restylane Kysse*.
- Age and pregnancy – *Restylane Kysse* has not been studied in patients under 22 years of age, patients who are pregnant or patients who are breastfeeding. If you are pregnant, trying to become pregnant, or breastfeeding, the safety and effectiveness of *Restylane Kysse* has not been proven in patients like yourself.
- Vision changes - Vision abnormalities have rarely been reported after treatment with other dermal filler gel treatments.
- Use of other skin therapies - The safety of *Restylane Kysse* has not been established in patients who have had other skin therapies, such as laser, mechanical, or chemical peeling, and hair removal. If you use *Restylane Kysse* with any of these skin therapies you may experience other side effects such as redness, swelling, heat and/or pain of the skin (inflammation).
- Ultraviolet (UV) exposure - You should avoid exposing the area(s) treated with *Restylane Kysse* to excessive sun, UV lamps or indoor tanning beds/booths, and extreme heat and cold until any redness or swelling has disappeared. Exposure to UV sources may result in irritation at the site of treatment.
- One of the risks of *Restylane Kysse* is that it may be unintentionally injected into a blood vessel during the procedure. 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, or blindness
 - stroke
 - temporary scabs
 - permanent scarring of the skin

You should tell your doctor immediately if you experience any of these side effects or if you notice anything unusual at the site of treatment. There are also other potential side effects that can occur with dermal filler gel injections. Although most side effects will resolve with time, some side effects may persist longer than 30 days. Your doctor may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase** (an enzyme that breaks down **HA**). You should discuss the potential treatment risks and benefits with your doctor.

8. BEFORE PROCEDURE INFORMATION

What happens in the office before the injection?

Note that each doctor may have a unique process for treating patients.

The following is an example of what your doctor may do before the injection procedure.

- Talk to you about your medical history, including questions about prior procedures, surgeries, illnesses and medications you have taken.
- Talk to you about your desired results for your procedure.
- Examine your face and discuss whether *Restylane Kysse* is the right treatment for you.
- Review what you should expect during and after the procedure.
- Let you know of any possible side effects that you may experience, and what to do if you experience these.
- Take photos of the area of your face that will be treated.

Your doctor may also have additional ways of evaluating patients and preparing them for a procedure.

9. PROCEDURE DESCRIPTION

What happens during the procedure?

Your doctor may do the following during your procedure:

- Your skin will be cleansed prior to treatment
- Use a cream or ointment called a topical **anesthetic** to numb the area where you will receive your injection.
- Your doctor will begin the procedure by giving you the first injection, then pausing to allow the **anesthetic** that is part of *Restylane Kysse* to continue to numb the area around your injection. The **anesthetic** part of *Restylane Kysse* has been shown to significantly reduce the pain and discomfort that may occur with a dermal filler gel injection.
- Your doctor will continue the injection of *Restylane Kysse* until the area being treated shows the desired results.
- After the injection is completed, your doctor may gently massage the area that was treated to ensure the dermal filler gel is distributed evenly and looks natural.

10. AFTER PROCEDURE INFORMATION

What should patients do after receiving treatment?

- A clean cloth dipped in cold water (cold compresses) wrung out, and applied to the injected area may be used immediately after treatment to reduce swelling.
- Avoid touching the treated area within six hours following treatment so you do not accidentally injure your skin while the area is numb. After that, the area can be gently washed with soap and water.
- Avoid taking aspirin, NSAID, St. John's Wort, blood thinners, and high doses of Vitamin E supplements for one week after treatment. These agents may increase bruising and bleeding at the injection site.
- Minimize strenuous exercise and exposure to excessive heat, sun, or UV lamps for the first 24 hours after treatment. Exposure to any of these may cause temporary redness, swelling, and/or itching at the injection site. Until there is no redness or swelling, avoid exposure of the treated area to intense cold or heat such as sun lamps or sun bathing.

11. ALTERNATIVE PROCEDURES

What other treatments are available to me?

There are other dermal filler gels in the United States that are available to you for treatment. Additionally, there are alternative treatments such as botulinum toxins, laser therapy and chemical peels for the treatment of lines and wrinkles. You can discuss these treatments with your doctor to determine which one is right for you.

12. WHEN TO CALL YOUR DOCTOR

When should I call my doctor?

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)
(<http://www.nlm.nih.gov/medlineplus/stroke.html>)
- 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 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

- Significant pain away from the injection site
- Any side effect that occurs weeks or months after treatment
- Any other symptoms that cause you concern.

13. ADDITIONAL INFORMATION

What if I experience a problem?

If you believe that you have experienced a serious problem related to *Restylane Kysse* you should call your doctor. Your questions about *Restylane Kysse* can be personally answered by contacting the Galderma Laboratories L.P. toll-free call center between 8:00 a.m. and 5:00 p.m. Central Daylight Time, Monday to through Friday.

1-855-425-8722

Galderma (logo)

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1 Conclusion

The content of the Patient Brochure has been approved by the US Food and Drug Administration.

2 Change information

Rational (ex. CC-No)	Measure	Chapter	Free text
			New document

a = added, c = changed, d = deleted