

Restylane-L[®]

Patient Brochure

Restylane-L[®]

Injectable Gel with 0.3% Lidocaine

Table of Contents

<i>About Restylane-L</i>	4
Safety	6
Post-Marketing Surveillance	9
About the Procedure	10
Troubleshooting	11

About Restylane-L

Q What is Restylane-L?

A *Restylane-L*® is a crystal clear injectable gel composed of hyaluronic acid, a natural substance that already exists in the body. *Restylane-L* is nonanimal based and free from animal protein. Allergy pretesting is not necessary. *Restylane-L* contains 0.3% lidocaine. The lidocaine in *Restylane-L* has been added to reduce the discomfort associated with the treatment.

Q How does Restylane-L work?

A *Restylane-L* is injected into the skin with an ultrafine needle to plump the skin to smooth away wrinkles and folds such as the lines from your nose to the corners of your mouth (nasolabial folds) or into your lips for patients over the age of 21 for lip enhancement.

Q Why add Lidocaine to Restylane?

A Lidocaine was added to *Restylane-L* to reduce the pain and discomfort during and after injection.

In a clinical study, 60 patients received *Restylane*® on one side of the face and *Restylane-L*® on the other side of the face. *Restylane-L* had an effect on reducing pain. At the time of injection, patients rated their pain about 45 on a scale of 0 to 100 for the side of the face treated with *Restylane*. In comparison, patients rated their pain about 15 on the same scale for the side of the face treated with *Restylane-L*. Patients reported less pain on the side of the face treated with *Restylane-L* up to 60 minutes after treatment.

Q How long does Restylane-L last?

A *Restylane-L* effects generally last about six months and gradually disappears from the body.

Q Has Restylane-L been studied?

A A clinical study was conducted with *Restylane-L* to evaluate the pain reducing effect up to 60 minutes after injection. This study enrolled 60 patients with moderate to severe nasolabial fold wrinkles. The study included 58 female patients and 2 male; 34 were White, 21 were Hispanic or Latino, 3 were African American, 1 was Asian, and 1 was “Other”.

In this study 71.7% of patients experienced less pain after injection of *Restylane-L* than with *Restylane* alone. Please see the below table for additional information.

Timepoint	Number of patients with pain reduction	
	No.	%
After Injection	43/60	71.7
15 Minutes	28/60	46.7
30 Minutes	17/60	28.3
45 Minutes	10/60	16.7
60 Minutes	4/60	6.7

In addition to evaluating the pain reducing effects, the study assessed patient satisfaction with *Restylane-L* treatment. All 60 subjects were asked to rate the level of improvement seen in their nasolabial folds after injection with *Restylane-L*. At day fourteen after injection 100% saw some improvement (Improved, Much Improved, and Very Much Improved). See below table for additional details.

Category	<i>Restylane-L</i>	
	Number of Patients	%
Very Much Improved (4)	17	28.3
Much Improved (3)	29	48.3
Improved (2)	14	23.3
No Change (1)	-	0.0
Worse (0)	-	0.0

Safety

Q Who should not use *Restylane-L* (Contraindications)?

A Safety has not been established and should not be used in people who are:

- Pregnant
- Breast feeding
- Trying to become pregnant
- Under the age of 22 for lip enhancement
- Under the age of 18 or over the age of 65
- Highly allergic (for example: gram positive bacteria)
- Prone to bleeding disorders

Q What are some warnings to consider?

A The use of *Restylane-L* at sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of *Restylane-L* in these instances could delay healing or make your skin problems worse.

You may experience skin discoloration (bruising), swelling, redness, tenderness, pain, itching, or small lumps in the area where you are injected. If any of these events occur, the majority usually last one to two weeks. If any symptom lasts longer than two weeks, call the doctor who administered the *Restylane-L* injection.

Red or swollen small bumps (inflammatory papules) may rarely occur. You may need antibiotics to treat them.

In clinical studies swelling was higher in younger patients (28%) compared to older patients (18%) and bruising was higher in older patients (28%) compared to younger patients (14%). The majority of these events were mild.

If you are injected with *Restylane-L* into your lips, your physician should be able to feel the product when touching your lips.

Q What are some potential risks you may encounter?

A As with all procedures like this, the injection of *Restylane-L* carries a risk of infection and formation of scar tissue.

The safety and effectiveness of *Restylane-L* has not been established in pregnant or nursing mothers, and in patients under 18 or over 65 years of age. *Restylane-L* use while nursing could harm you or the nursing child. *Restylane-L* should not be used for lip enhancement in patients under the age of 22.

The use of *Restylane-L* in African-American patients can result in darkening of skin color (hyperpigmentation), which may take several weeks to correct.

If you have previously had facial cold sores, an injection can cause them to come back.

The safety of *Restylane-L* used with other skin therapies such as laser, mechanical or chemical peeling, and hair removal has not been established. The use of *Restylane-L* with these skin therapies may lead to other side effects such as inflammation.

You should avoid exposing the area(s) treated with *Restylane-L* to excessive sun or UV lamps, and extreme heat and cold until any redness or swelling has disappeared.

Clinical volunteers keeping diaries reported the following short-lived events:

Restylane-L was evaluated in a clinical study of 60 patients. The below table shows what patients reported each day after injection of *Restylane-L* in the diary they kept. The most common events were: pain, swelling, redness, tenderness, bruising, itching and other. The reporting of these events decreased over time and by day 14 most events had resolved.

	Total (%)	Number of days			
		1	2–7	8–13	14
Bruising	58.3%	8.6%	80.0%	11.4%	0.0%
Redness	50.0%	33.3%	56.7%	6.7%	3.3%
Swelling	66.7%	10.0%	72.5%	17.5%	0.0%
Pain	45.0%	48.1%	40.7%	3.7%	7.4%
Tenderness	68.3%	31.7%	48.8%	12.2%	7.3%
Itching	13.3%	87.5%	12.5%	0.0%	0.0%
Other	6.7%	0.0%	50.0%	0.0%	50.0%

Q What are some benefits from clinical evaluation?

A In one study in which 135 patients received *Restylane* injections in their lips, two weeks after the injection 96% of the patients said their lips were improved compared to before the injection. At least 74% of the patients still saw an improvement in their lips at 6 months after the injection.

Post-Marketing Surveillance:

Q Have there been adverse events reported through post-market surveillance?

A Serious adverse events have been rarely reported. The only serious adverse events occurring in a frequency of 5 times or greater were abnormal sensitivity (hypersensitivity), injury to blood supply (vascular accidents), local tissue damage (necrosis) and infection/abscess. Hypersensitivity reactions have occurred immediately following implantation and up to 3 weeks and some required hospitalization. Reported symptoms included swelling (including severe swelling of lips and face); redness; itching on chest and back; puffy, burning, watery, and itchy eyes; shortness of breath; headache; nausea and vomiting. Treatments used included steroids, diphenhydramine, unspecified intravenous medication, oxygen and various creams. Most hypersensitivity events have resolved within 1 to 14 days with or without treatment. Bruising and skin turning white as a result of injury to blood supply (blanching) have occurred immediately following injection with some cases resulting in necrosis. As a result of the necrosis some patients experienced scarring and dark spots on the skin. Moderate to severe infection/abscess formations have occurred with an onset ranging from 3 days to one week post injection with approximately one month to resolution. Symptoms included swelling, redness, pain and hard nodules. Some patients required hospitalization for incision and drainage and intravenous (IV) antibiotic therapy. Culture results for the reports of infection or abscess varied. Treatment included various antibiotics and steroids in some cases.

Adverse events that have occurred at the injection sites include: discoloration, bruising, swelling, lumps/bumps, redness, pain, scarring, numbness/tingling, necrosis, and low blood supply due to blockage of a blood vessel (ischemia). Additional events include: bacterial infections, fainting (vasovagal reactions), herpetic eruptions, dilated small blood vessels (broken capillaries), and inflammatory reactions (swelling, redness, tenderness, hardness and acneform papules).

About the Procedure

Q What are the serious side effects?

A Rarely, the doctor may accidentally inject the product into a blood vessel, which can cause injury to the blood supply and damage to the skin or lips.

Rarely, a few people have developed infections that must be treated with antibiotics or other treatment. Infection may be hard to treat, but will generally go away when the gel is absorbed.

Q What should patients do prior to treatment?

A *Restylane-L* requires no pretesting, but you should take a few precautions before being treated. Avoid using St. John's Wort, high doses of Vitamin E supplements, aspirin, and other non-steroidal anti-inflammatory medications, such as ibuprofen prior to treatment, because these may increase bruising or bleeding at the injection site. Please speak to your doctor about when to stop these medications before your procedure. Also, if you have previously suffered from facial cold sores, discuss this with your physician. He or she may consider prescribing a medication to minimize recurrences.

Q What is the dose of *Restylane-L*?

A The amount used depends on your face and what you would like to have treated. The average patient who has all of the severe wrinkles around the mouth or lips corrected will use less than half a tablespoon.

Please speak to your doctor to determine the correct amount of product needed.

Q Do the injections hurt?

A *Restylane-L* is injected directly into the skin with an ultrafine needle. To help maximize your comfort, you should discuss the use of numbing medicines with your doctor before treatment.

Q How much does *Restylane-L* treatment cost?

A *Restylane-L* is a customized procedure based on your specific needs, so the cost will vary from patient to patient. In general, the cost of *Restylane-L* is similar to the cost of similar procedures. Please ask your doctor to give you an estimate of the cost.

Q Are there post-treatment instructions to follow after a *Restylane-L* treatment?

- A** Please observe the following after treatment with *Restylane-L*:
- A 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.
 - Until there is no redness or swelling, avoid exposure of the treated area to intense heat such as sun lamps or sun bathing.
 - If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another occurrence. Speak to your physician about medicine to prevent this from happening again.

Avoid taking aspirin, non-steroidal anti-inflammatory medications, St. John's Wort, and high doses of Vitamin E supplements for one week after treatment. These agents may increase bruising and bleeding at the injection site.

Troubleshooting

Q When should I call my doctor?

A Most side effects like bruising, swelling, pain, tenderness, redness, and itching will usually go away within one to two weeks. Call your doctor if you have persistent problems beyond 14 days.

Blisters or skin sores that recur may signal the presence of a herpes infection that must be treated.

You can develop an infection that should be treated with antibiotics. If you experience any signs of infection such as fever, redness that spreads to surrounding areas, drainage, increasing tenderness, or increasing pain that does not go away you should call your doctor.

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User Assistance Information

Your questions about *Restylane-L* can be personally answered by contacting the Medicis toll-free call center, 24 hours per day, 7 days per week.

1-800-900-6389



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13120243 Revised 08/2012