

[Cover – page 1]

Restylane® Lyft with Lidocaine

Patient Brochure

[Inside Cover – page 2]

Restylane® Lyft Injectable Gel with 0.3% Lidocaine

[Page 3]

Table of Contents

[Page 4]

Frequently Asked Questions

Product Description

What is Restylane® Lyft with Lidocaine?

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

How does Restylane® Lyft with Lidocaine work?

Restylane® Lyft with Lidocaine 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 and to increase the fullness of your cheeks.

Why is there lidocaine in Restylane® Lyft with Lidocaine?

The lidocaine in *Restylane® Lyft with Lidocaine* reduces pain and discomfort during and after injection.

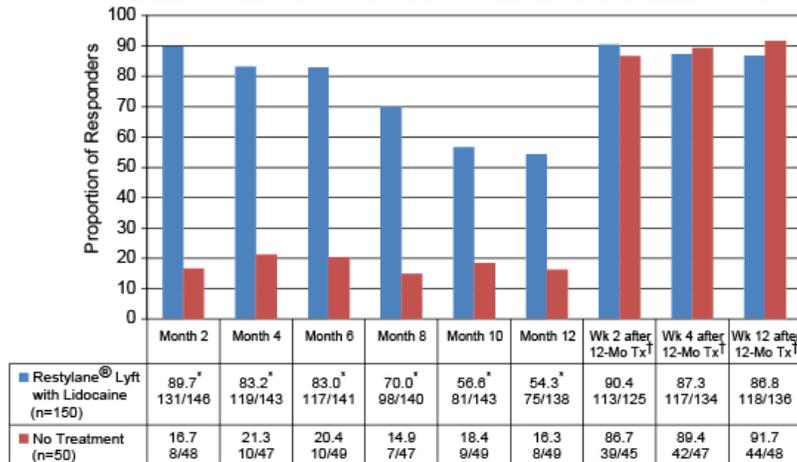
The effectiveness of the lidocaine was studied in a split-face clinical study of 60 patients. Each patient received *Restylane® Lyft without lidocaine* on one side of the face and *Restylane® Lyft with lidocaine* on the other side of the face for the treatment of lines around the nose and mouth. *Restylane® Lyft with lidocaine* significantly reduced the pain of the injection.

- For the side of the face treated with *Restylane*[®] *Lyft without lidocaine*, patients rated their pain as about 47 on a scale of 0 to 100 after injection.
- For the side of the face treated with *Restylane*[®] *Lyft with lidocaine*, patients rated their pain as about 15 on the same scale.
- Pain relief from the lidocaine in *Restylane*[®] *Lyft with Lidocaine* lasted up to 60 minutes after treatment.

How long does *Restylane*[®] *Lyft with Lidocaine* last?

- When *Restylane*[®] *Lyft with Lidocaine* is used for the treatment of wrinkles and folds such as the lines from your nose to the corners of your mouth, the benefits generally last about 6 months as the filler gradually disappears from the body.
- When *Restylane*[®] *Lyft with Lidocaine* is used to increase the fullness of your cheeks, the benefits generally last between two and twelve months as the filler gradually disappears from the body. The graph below compares patients who were treated with *Restylane Lyft with Lidocaine* and patients who had no treatment, who showed a positive treatment response at 2, 4, 6, 8, 10 and 12 months, as assessed by blinded evaluators (e.g., physicians not aware of the patient treatment assignment).

Proportion of Patients Who Showed a Positive Treatment Response Measured by Blinded Evaluator's Assessment for Fullness of Cheeks



*The difference between Restylane Lyft with Lidocaine and no treatment was statistically significant ($P < .001$) at each time point between month 2 and month 12 after treatment.

†All subjects (both 'Restylane® Lyft with Lidocaine and 'No Treatment') were treated with Restylane® Lyft with Lidocaine by the Week 2 after 12-Month, Week 4 after 12-Month, and Week 12 after 12-Month visits. Wk = Week; Mo = Month; Tx = Treatment

Note: All subjects treated at the Month 12 Treatment visit received an injection with Restylane® Lyft with Lidocaine. This was the first treatment for the 'No Treatment' subjects and the second treatment for the 'Restylane® Lyft with Lidocaine' subjects.

Note: Response is defined as improvement of at least one grade in MMVS assessments from the baseline Blinded Evaluator's value to the Blinded Evaluator's assessment for the week of interest.

Note: The Proportion of Responders is calculated as the number of Responders at the visit of interest divided by the number of subjects in the ITT population for the specified treatment group with a non-missing assessment for the specified visit.

Note: P-values for the difference in proportions in Restylane® Lyft with Lidocaine and No Treatment are based on the Fisher's Exact test.

Note: 95% Confidence Intervals are two-sided confidence intervals calculated using the exact binomial distribution.

[Page 5]

Effectiveness

What were the outcomes in the clinical trials?

Restylane[®] *Lyft without Lidocaine* and *Restylane*[®] *Lyft with Lidocaine* were tested in several clinical trials for each of its intended uses.

For the treatment of wrinkles around the nose and mouth, *Restylane*[®] *Lyft without lidocaine* was tested in 4 prospective randomized controlled clinical trials involving 509 *Restylane*[®] *Lyft without lidocaine* –treated patients.

- Patients reported significant improvement in the appearance of the wrinkles and folds around the mouth that lasted for 6 months.

The effectiveness of the lidocaine in *Restylane*[®] *Lyft with Lidocaine* was studied in a split-face, clinical study of 60 patients. Each patient received *Restylane*[®] *Lyft without lidocaine* on one side of the face and *Restylane*[®] *Lyft with Lidocaine* on the other side of the face for the treatment of lines around the nose and mouth.

- *Restylane*[®] *Lyft with Lidocaine* significantly reduced the pain of the injection for up to 1 hour after treatment.

For the treatment of cheeks, *Restylane*[®] *Lyft with Lidocaine* was tested in a prospective clinical trial of 200 patients.

- Patients reported significant improvements in the appearance of their cheeks that generally lasted between 2 and 12 months.

More information about the safety outcomes from these trials is in the following section.

[Page 6]

Safety

Are there any reasons why I should not use *Restylane*[®] *Lyft with Lidocaine*? (Contraindications)

To ensure a safe procedure, your doctor will talk to you about your medical history to determine if you are an appropriate candidate for treatment. You should not use *Restylane*[®] *Lyft with Lidocaine* if:

- You have severe allergies with a history of severe reactions (anaphylaxis). An injection of *Restylane® Lyft with Lidocaine* may result in an allergic reaction.
- You are allergic to lidocaine or to any of the proteins used to make the hyaluronic acid in *Restylane® Lyft with Lidocaine* (bacterial proteins). An injection of *Restylane® Lyft with Lidocaine* may result in an allergic reaction.
- You are prone to bleeding or have been diagnosed with a bleeding disorder. An injection of *Restylane® Lyft with Lidocaine* may have a higher risk of severe bleeding or bruising.

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

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

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

- Which areas of the face you would like to have treated
 - *Restylane® Lyft with Lidocaine* is intended for use in the areas around the nose, mouth, and cheeks. Results have not been studied in other areas of the face in the United States.
 - The use of *Restylane® Lyft with Lidocaine* on gel injection sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of *Restylane® Lyft with Lidocaine* in these areas of skin could delay healing or make your skin problems worse.
- If you are of appropriate age to receive *Restylane® Lyft with Lidocaine*
 - For injections around the nose and mouth, the safety of *Restylane® Lyft with Lidocaine* has not been studied in people younger than 18 years or older than 65 years.
 - For injections to the cheek, safety has not been studied in patients younger than 22 years.
- If you are breastfeeding, pregnant, or trying to become pregnant
 - The safety of *Restylane® Lyft with Lidocaine* for use during pregnancy, or in women who are breastfeeding, has not been studied.
- If you are on any medications to decrease your body's immune response (immunosuppressive therapy)
 - Use of these medications may increase your risk of infection.
- If you are using any "blood thinners" such as aspirin, warfarin, or any other medications that affect bleeding
 - Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- If you have any history of scarring, particularly thick and stiff scars, or any pigmentation (skin color) disorders. These side effects can occur with hyaluronic acid fillers in general

- In clinical trials of *Restylane*[®] *Lyft with Lidocaine*, some African-American patients experienced a darkening of skin tone (hyperpigmentation) that resolved after 6 weeks.
- No excessive scarring (keloids) was reported by clinical trial patients across different skin tones (pale to dark).

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

[Page 7]

What are possible side effects after an injection of *Restylane*[®] *Lyft with Lidocaine*?

It is important to understand that any procedure carries a risk of side effects. An injection of dermal filler can have two sources of skin reactions: from the injection itself and from the dermal filler.

Based on the clinical trials, you may experience skin discoloration (bruising), swelling, redness, tenderness, pain, itching, or small bumps in the area where you are injected as well as a headache. If any of these side effects occur, the majority are mild to moderate reactions that disappear within a week or two. If any symptom lasts longer than 2 weeks, you should call your doctor.

Greater than or equal to 3% of patients had the following delayed reaction at the site of injection up to 138 days after treatment:

- Redness
- Bruising
- Inflammation
- Bumps
- Pain
- Swelling
- Warmth
- Hardening

What are some potential risks that I may encounter?

Other potential risks may arise from an injection of a dermal filler such as *Restylane*[®] *Lyft with Lidocaine* including the following:

- Infection - Facial skin injections, including those with *Restylane*[®] *Lyft with Lidocaine*, are associated with a risk of infection. As with any infection, there may be a need for your doctor to prescribe antibiotics. Though rare, a skin infection could appear as small, swollen (or red) bumps (inflammatory papules).

If an infection worsens over time, you should contact your doctor for further treatment.

- Scarring - While it is very rare, scarring may occur with an injection procedure. In clinical trials, excessive scarring (keloids) was not observed in any of the patients receiving *Restylane[®] Lyft with Lidocaine*.
- Change in skin tone - If you are African American, you may have a higher risk of darkening of the skin tone in the treated area (hyperpigmentation). This may take several weeks to disappear. In clinical trials, this change in skin tone did not occur with injection of *Restylane[®] Lyft with Lidocaine* into the cheeks.
- Cold sores - If you have had cold sores in the past, there is a risk that they will return as a result of facial injections.
- Age and pregnancy - If you are under 18 or over 65 years of age, are pregnant or trying to become pregnant, or are nursing, you should know that the safety and effectiveness of *Restylane[®] Lyft with Lidocaine* has not been established in patients like yourself. In addition, for treatment of the cheeks, *Restylane[®] Lyft with Lidocaine* has not been evaluated in patients younger than 22 years of age.
- Vision changes - Rarely, vision abnormalities have been reported after treatment with *Restylane[®] Lyft with Lidocaine*.
- Use of other skin therapies - The safety of *Restylane[®] Lyft with Lidocaine* used with other skin therapies such as laser, mechanical or chemical peeling, and hair removal has not been established. The use of *Restylane[®] Lyft with Lidocaine* with these skin therapies may lead to other side effects such as inflammation.
- Ultraviolet (UV) exposure - You should avoid exposing the area(s) treated with *Restylane[®] Lyft with Lidocaine* 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.

If you have any additional questions or concerns about these potential risks, please discuss them with your doctor.

[Page 8]

What were the side effects reported by patients in the clinical trials?

After the injection, most patients reported redness, swelling, bruising, lumps/bumps, pain/tenderness, or itching at the gel injection site. Most side effects were mild and short-lived, did not require medical attention, and disappeared within 1 to 2 weeks. In addition, the lidocaine (anesthetic) in *Restylane[®] Lyft with Lidocaine* significantly reduced pain during and after treatment.

Table 3 below shows what patients reported in their trial diaries after injection of *Restylane[®] Lyft with Lidocaine* to treat wrinkles and folds around the nose and mouth.

Table 3: Duration of Patient Reported Adverse Events After Treatment of Lines Around the Nose and Mouth

Restylane® Lyft with Lidocaine Patients Reporting Symptoms (%)					
	Total n (%)	By Number of Days With Symptoms			
		1	2-7	8-13	14
Bruising	36 (60.0%)	6 (16.7%)	27 (75.0%)	3 (8.3%)	0 (0.0%)
Redness	34 (56.7%)	9 (26.5%)	24 (70.6%)	0 (0.0%)	1 (2.9%)
Swelling	42 (70.0%)	4 (9.5%)	33 (78.6%)	4 (9.5%)	1 (2.4%)
Pain	28 (46.7%)	17 (60.7%)	11 (39.3%)	0 (0.0%)	0 (0.0%)
Tenderness	50 (83.3%)	6 (12.0%)	40 (80.0%)	4 (8.0%)	0 (0.0%)
Itching	16 (26.7%)	5 (31.3%)	10 (62.5%)	1 (6.3%)	0 (0.0%)
Other	3 (5.0%)	0 (0.0%)	3 (100.0%)	0 (0.0%)	0 (0.0%)

In a clinical study of 200 patients for the treatment of cheek fullness with *Restylane® Lyft with Lidocaine*, patients were asked to score the duration of pain, tenderness, redness, bruising, swelling, and itching. Table 4 below shows what patients reported in their trial diaries during this study. Bruising lasted longer than other side effects, and within 2 weeks most events had resolved.

Table 4: Duration of Patient Reported Symptoms after Treatment for the Fullness of Cheeks

	By No. of Days With Symptoms			
	1 n (%)	2 - 7 n (%)	8 - 13 n (%)	14 n (%)
Right and Left Cheek Combined (N=199)				
Pain (including burning)	34 (22%)	109 (69%)	12 (8%)	2 (1%)
Tenderness	17 (9%)	112 (59%)	47 (25%)	13 (7%)
Redness	39 (25%)	96 (62%)	18 (12%)	2 (1%)
Bruising	10 (6%)	66 (40%)	70 (43%)	17 (10%)
Swelling	14 (8%)	132 (74%)	26 (15%)	7 (4%)
Itching	16 (24%)	42 (63%)	9 (13%)	0

What are the major side effects?

Rarely, the doctor may inadvertently inject the product into a blood vessel, which can cause injury to the blood supply and damage to the skin, or vision abnormalities including blindness.

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

In clinical trials, 2 patients reported 4 serious adverse events (SAEs) that were considered to be related to the device and/or the procedure. One subject reported gel injection site swelling (late onset inflammatory reactions) in both cheeks at separate times. Treatments for the left and right cheeks each included antibiotics, nonsteroidal anti-inflammatory medications (such as ibuprofen and naproxen) and hyaluronidase (a medicine to help break down the *Restylane*[®] *Lyft with Lidocaine* so that it is more easily absorbed). The second patient experienced gel injection site bruising (hematoma) in the right cheek and gel injection site infection/abscess. Treatment of the right cheek infection/abscess and gel injection site bruising included antibiotics and a surgical procedure (incision and drainage). All events resolved with treatment and time.

Product Safety Monitoring:

Have there been adverse events reported through product safety monitoring?

The adverse events received from product safety monitoring for the use of *Restylane*[®] *Lyft with Lidocaine* when used outside the US to increase the fullness of the cheek were infrequent and included mostly reports of swelling and mass/induration (hardening). Serious adverse events which occurred ≥ 5 times were the following, in descending order of frequency:

- Swelling at treatment location
- Abscess at treatment location
- Infection at treatment location
- Redness at treatment location
- Discharge of pus at treatment location
- Bumps (nodules) at treatment location
- Medical device implantation (events reported as overcorrection, overfill, skin depression, or irregular skin)

The incidence of post market events potentially related to treatment with *Restylane*[®] *Lyft with Lidocaine* for all indications and that occurred in greater than five patients included the following, in descending order of frequency:

- Swelling
- Device ineffective
- Accidental exposure
- Mass/induration (hardening)
- Nondermatological events
- Skin redness
- Pain/tenderness
- Infection/abscess

- Bruising/abscess
- Bruising/bleeding
- Papules/nodules (bumps under the skin)
- Inflammation
- Neurological symptoms
- Medical device implantation (events reported as overcorrection, overfill, skin depression, or irregular skin)
- Gel injection site reactions
- Hypersensitivity
- Itching
- Discoloration
- Eye disorders
- Restricted blood flow leading to the death of skin (ischemia/necrosis)
- Scar/scab/skin atrophy
- Procedural complications
- Herpes
- Device dislocation
- Device misuse
- Rash

Reported treatments have included steroids or antibiotics administered intravenously, orally or by injection. Serious adverse events have been rarely reported. The most commonly reported serious adverse events were hypersensitivity, and gel injection site swelling, restricted blood flow leading to the death of skin and discoloration. Serious abscess formations have also been reported.

Gel injection site reactions, mostly non-serious events, have also been reported. These include:

- Discoloration
- Bruising
- Swelling
- Mass formation
- Skin redness
- Pain
- Scarring
- Restricted blood flow leading to the death of skin (ischemia)

Most instances of discoloration including darkening skin tone (hyperpigmentation), sometimes described as a blue or brown color and ranging from mild to severe, have occurred within the same day as treatment but have also occurred up to 6 months post treatment. These events typically resolve within a few days but with some infrequent instances lasting up to 18 months. Gel injection site bruising, swelling, skin redness and pain generally occurred on the same day as treatment usually resolving within 1 to 4 weeks. Some occurrences have persisted for up to 6 months. Severity for these events is generally mild to moderate although some cases have been severe.

Warning: 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. 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, you should notify your health care practitioner immediately.

Injection and Administration

What should I do before treatment?

Restylane[®] *Lyft with Lidocaine* requires no allergy pretesting. However, before you undergo treatment with *Restylane*[®] *Lyft with Lidocaine*, you should take the following precautions:

- Avoid using the following products, because these may increase bruising or bleeding at the gel injection site:
 - St. John's Wort
 - High doses of vitamin E supplements
 - Nonsteroidal anti-inflammatory medications (such as aspirin or ibuprofen)

- If you have previously suffered from facial cold sores, discuss this with your doctor. Your doctor may consider prescribing a medication to minimize recurrences.

What is the dose of *Restylane*[®] *Lyft with Lidocaine*?

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 corrected will use less than half a tablespoon. Most patients getting *Restylane*[®] *Lyft with Lidocaine* for the fullness of cheeks may require a larger dose. Based on U.S. clinical studies, the recommended dose per treatment should not exceed 6.0 mL which is less than half a tablespoon.

Do the injections hurt?

As with all injections, there may be pain or discomfort during the procedure.

Restylane[®] *Lyft with Lidocaine* contains lidocaine, a local anesthetic, to reduce the pain or discomfort associated with an injection. In addition, *Restylane*[®] *Lyft with Lidocaine* is injected directly into the skin in tiny amounts by an ultrafine needle.

To help maximize your comfort, you should discuss the use of numbing medicines with your doctor before treatment.

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

Most side effects like bruising, swelling, pain, tenderness, redness, and itching will usually go away within 2 weeks. Call your doctor if you have persistent problems beyond 14 days.

You can develop an infection that should be treated with antibiotics. If it gets worse, you may need other treatments, such as surgery. If you experience redness, tenderness, and pain that do not go away in 2 weeks, you should call your doctor.

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

Seek immediate medical attention if you develop symptoms such as unusual pain, vision changes, a white appearance of skin near the injection site, or any 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) during or shortly after the procedure (<http://www.nlm.nih.gov/medlineplus/stroke.html>).

Is there a post-treatment checklist to follow after a *Restylane*[®] *Lyft* with Lidocaine treatment?

Consider the following after treatment with *Restylane*[®] *Lyft* with Lidocaine:

- Cold compresses (a cloth dipped in cold water, wrung out, and applied to the injected area) may be used immediately after treatment to reduce swelling.
- Avoid touching the treated area within 6 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 exposure of the treated area to intense heat (sun lamp or sun bathing) until there is no redness or swelling.
- 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 1 week after treatment. These agents may increase bruising and bleeding at the gel injection site.

Restylane[®] *Lyft* with Lidocaine

User Assistance Information

Your questions about *Restylane® Lyft with Lidocaine* 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 through Friday.

1-855-425-8722

Galderma (logo)

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Revised 06/2015