Patient Brochure

Restylane® Lyft Injectable Gel with 0.3% Lidocaine

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Glossary

(Note: words in the glossary are in bold throughout this document)

- **Anesthetic** – a substance that reduces sensitivity to pain.
- **Cannula** – a thin metal tube with a blunt tip. It may be used as an alternative to needles in treatment in the cheeks or midface.
- **Hyaluronic acid (HA)** – a polysaccharide (sugar) that is naturally in the body. It keeps skin moisturized and soft. **HA** fillers, including *Restylane Lyft with **Lidocaine***, are a modified form of the **HA** that is naturally in your body.
- **Hyaluronidase** – a medicine used to breakdown **HA** in the area of injection.
- **Lidocaine** – a medication used to numb a specific area to decrease pain.
- **NSAID** – Nonsteroidal anti-inflammatory drug, such as ibuprofen.
- **Touch-up** – an additional injection of a small amount *Restylane Lyft with **Lidocaine*** usually given two weeks after treatment, if necessary to achieve the desired result.
- **BDDE** – the ingredient used to crosslink the **HA**.
- **Crosslinked** – a process in which **HA** chains are connected together to form a network.

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 **crosslinked** with **BDDE,** an ingredient that helps form a network of **HA** to provide a gel filler that lasts longer. *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 is injected with an ultrafine needle or a small, blunt-tipped **cannula** to increase the fullness of your cheeks. *Restylane Lyft with* ***Lidocaine*** may also be injected, using an ultrafine needle under the skin to address volume deficiency in the back of the hand.

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.

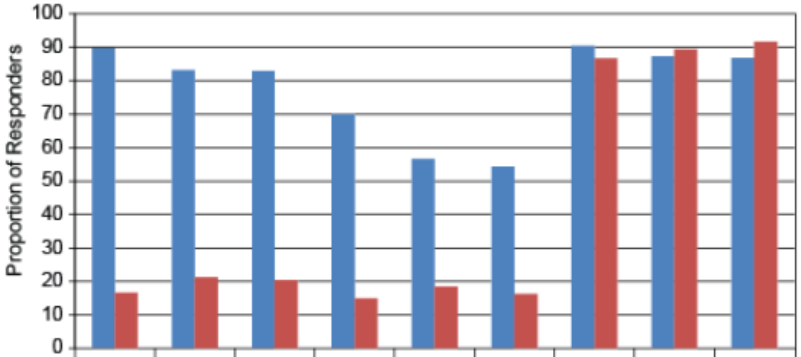
- For the side of the face treated with *Restylane® Lyft without* ***Lidocaine***, patients rated their pain as about 47 on a scale of 0 to 100 after injection.
- For the side of the face treated with *Restylane® Lyft with* ***Lidocaine***, patients rated their pain as about 15 on the same scale.
- Pain 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*** using a needle 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



	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12	Wk 2 after 12-Mo Tx†	Wk 4 after 12-Mo Tx†	Wk 12 after 12-Mo Tx†
Restylane® Lyft with Lidocaine (n=150)	89.7* 131/146	83.2* 119/143	83.0* 117/141	70.0* 98/140	56.6* 81/143	54.3* 75/138	90.4 113/125	87.3 117/134	86.8 118/136
No Treatment (n=50)	16.7 8/48	21.3 10/47	20.4 10/49	14.9 7/47	18.4 9/49	16.3 8/49	86.7 39/45	89.4 42/47	91.7 44/48

**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.

- When *Restylane® Lyft with* ***Lidocaine*** is used to increase fullness in the back of the hand, the benefits usually lasts 6 months as the filler gradually disappears from the body.

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 using a needle, *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.

For treatment in the cheek using a **cannula**, *Restylane® Lyft with* ***Lidocaine*** was tested in a multicenter 16-week study of 60 patients.

- Results demonstrated improvement in the appearance of the cheeks from the initial treatment for all or almost all subjects at each follow up visit.

For the treatment of volume deficit in the back of the hand, *Restylane® Lyft with* ***Lidocaine*** was tested in a multi-center, randomized, evaluator-blinded, paired (split-hand) study with 89 patients who were injected using a needle.

- Patients reported improvements in the appearance of their hands that lasted 6 months.
- A separate group of 25 patients were injected with **cannula**. Preliminary results indicate that **cannula** use was associated with higher treatment adverse events, delayed adverse events and reduced thumb movement (flexion) compared to needle injections. Therefore, it has not been established whether the benefits outweigh the risks of injecting *Restylane Lyft with* ***Lidocaine*** into the back of the hand using a **cannula**.

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

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?

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.

There are several other 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 would like to have treatment in the hands
    - Tell your doctor if you have had previous hand surgery including sclerotherapy or history of hand trauma.
    - History of Raynaud's disease or Raynaud's phenomenon, or history of other disease
- 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 and hands, 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 skin color (pigmentation) 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.

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.

In a clinical study on cheek injections using a needle, 3 people out of 100 (3%) had the following delayed injection site reactions 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.
- Thumb Function – You may experience a slight decrease in the flexibility of your thumb after treatment with *Restylane® Lyft with* ***Lidocaine*** in the back of your hand.

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

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*** using a needle, 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

In a clinical study of 89 patients for the treatment of volume loss in the dorsal hand with *Restylane® Lyft with* ***Lidocaine***, patients were asked to score the duration of pain, tenderness, redness, bruising, swelling, itching, and impaired hand function. Table 5 below shows what patients reported in their trial diaries during this study after initial treatment, and Table 6 shows in detail for how long each symptom lasted.

Table 5. Side effects after initial treatment, as reported in Patient Diaries

Side effect	**Experienced by**	**Remaining after one week in**
Swelling	75 out of 100 people (75%)	9 out of 100 people (9%)
Tenderness	74 out of 100 people (74%)	14 out of 100 people (14%)
Redness	71 out of 100 people (71%)	None
Bruising	60 out of 100 people (60%)	2 out of 100 people (2%)
Pain	45 out of 100 people (45%)	3 out of 100 people (3%)
Itching	13 out of 100 people (13%)	None
Impaired function	7 out of 100 people (7%)	None

Table 6. Duration of Patient Reported Symptoms after initial treatment

	Total number of patients with this symptom	**Number of patients With Symptoms at specified Time Intervals (Days)**				
		1 n (%)	2 – 7 n (%)	8 – 14 n (%)	15 – 21 n (%)	22 – 27 n (%)
Pain	40	19 (47.5%)	20 (50%)	none	none	1 (2.5%)
Tenderness	66	15 (22.7%)	42 (63.6%)	4 (6.1%)	2 (3.0%)	3 (4.5%)
Redness	63	27 (42.9%)	36 (57.1%)	none	none	none
Bruising	53	13 (24.5%)	39 (73.6%)	1 (1.9%)	none	none
Swelling	67	17 (25.4%)	44 (65.7%)	5 (7.5%)	1 (1.5%)	none
Itching	12	7 (58.3%)	5 (41.7%)	none	none	none
Impaired Function	6	4 (66.7%)	2 (33.3%)	none	none	none

n = the number of patients who experienced this reaction within the specified time interval
% = out of 100 people, the expected number of people who will experience this reaction for the number of days specified

Additionally, in the hand functionality testing after the treatment, 24.7% of subjects had a slight decrease in thumb flexion (bending their thumb) which remained throughout the 6-months study. However, for 10 of these 22 subjects, a decrease in the non-treated (fellow) hand was also observed.
In this study, one hand on each patient was injected with Restylane Lyft with Lidocaine at the start of the study, 4 weeks later for a touch-up for some of the patients, and at a 6-month Retreatment for some of the patients. The other hand was injected with Restylane Lyft with Lidocaine for the first time at 6-months into the study (Initial Treatment) and 4 weeks later for a touch-up for some of the patients. Similar pattern of injection site reactions were found at all treatment occasions, i.e. the incidence of injection site reactions decreased over the first week, and within 2 weeks most events had resolved.

In a clinical study of 60 patients for the treatment of cheek fullness with *Restylane® Lyft with* ***Lidocaine*** using a **cannula** for injection, patients were asked to report if they had pain, tenderness, redness, bruising, swelling, and itching during the first 2 weeks after each treatment. Table 7 below shows what patients reported in their trial diaries during this study.

Table 7. Side effects after treatment for the cheeks as reported in patient diaries: Restylane Lyft with Lidocaine using a cannula for injection[a]

1st Treatment[b]		2nd Treatment[c]	
Side effect	**Experienced by**	**Side effect**	**Experienced by**
Bruising	18 out of 60 people (30%)	Bruising	11 out of 43 people (26%)
Redness	26 out of 60 people (43%)	Redness	9 out of 43 people (21%)
Swelling	38 out of 60 people (63%)	Swelling	27 out of 43 people (63%)
Pain	36 out of 60 people (60%)	Pain	21 out of 43 people (49%)
Tenderness	55 out of 60 people (92%)	Tenderness	31 out of 43 people (72%)
Itching	11 out of 60 people (18%)	Itching	4 out of 43 people (9%)

[a]Clinical Study 43USC1633

[b]Based on 60 study patients who provided information about side effects after their 1st treatment

[c]Based on 43 study patients who provided information about side effects after their 2nd treatment about 4 months later

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, **NSAID** nonsteroidal anti-inflammatory medications (such as ibuprofen and naproxen) and a medicine to help break down the Restylane Lyft with Lidocaine so that it is more easily absorbed (**hyaluronidase**). 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). In the clinical trial for the hand, 4 patients with adverse events of swelling, small bump

(nodules) , or tenderness that were considered to be related to the device and/or the procedure received treatments that included antibiotics, **NSAID** nonsteroidal anti-inflammatory medications (such as ibuprofen and naproxen) and medicine used to help breakdown **HA** in the body (**hyaluronidase**). All events resolved with treatment and time.

What side effects have been voluntarily reported of *Restylane Lyft with Lidocaine* use in and outside of the United States?

The most common side effects included reports of transient swelling/oedema and inflammatory reactions with immediate onset or delayed onset, up to several weeks after treatment. The following events were also reported:

- Short duration of effect
- Hardening (mass/induration)
- Pain or tenderness
- Skin redness (erythema)
- Bruising (hematoma)
- Presumptive bacterial infections and pus (abscess formation)
- Small bumps (papules/nodules)
- Inflammation
- Injection site reactions including burning sensation, warmth and irritation
- Skin discoloration (hyperpigmentation)
- Reduced sense of touch (hypoaesthesia), tingling sensation (paraesthesia) and facial nerve paralysis
- Allergic reaction (hypersensitivity) and rapid swelling (angioedema)
- Restricted blood flow (ischemia/necrosis), eye pain, eye swelling, eye irritation, increased secretion of tears (increased lacrimation), drooping eyelid (eyelid ptosis) and visual impairment such as blurred vision, reduced visual acuity and blindness
- Itching (pruritus)
- Scarring
- Device displacement
- Rash
- Leakage from implant site (effusion/discharge)
- Small area of inflammation in tissue (granuloma)
- Acne
- Blisters/vesicles
- Symptoms of reactivation of herpes infection
- Hives (urticaria)
- Dilated small blood vessels (telangiectasia)
- Leakage of product from implant site (extrusion of device)
- Dermatitis
- Muscle disorders such as muscle twitching and muscle weakness
- Encapsulation of gel in the tissue
- Other dermatological events including dry skin, skin wrinkling, peeling of skin and localized hair loss (alopecia)
- Non-dermatological events including headache, discomfort (malaise), fever, dizziness, sinus infection, shortness of breath (dyspnea), feeling tired (fatigue), influenza like illness, insomnia, nausea and anxiety

In rare cases after treatment in the cheeks, a late onset of side effects (weeks to months after treatment) and recurrent inflammation was reported. The symptoms were small bumps or lumps, infection, and skin redness, swelling and pain. Treatments of these events included a medicine used to help break down **HA** in the body (**hyaluronidase**), antibiotics, drugs to reduce inflammation (corticosteroids), drugs to relieve pain (analgesics) and surgical procedure (incision and drainage).

The most commonly reported serious adverse events were infection/pockets of pus (abscess), restricted blood flow leading to the death of skin (ischemia/necrosis), vision loss, allergic reactions (hypersensitivity), scarring, areas of inflammation in tissue (granuloma) including cases of hardening (mass/induration). Other serious events included common related symptoms such as; swelling, pain/tenderness, skin redness (erythema), reduced sense of touch (hypoaesthesia), tingling sensation (paraesthesia), bruising, skin discoloration , small bumps (papules/nodules), and overcorrection, overfill and irregular skin.

- Serious infection and abscess (pus) were reported with a time to onset from one day to two months following the injection. Most of the patients were recovered or recovering at the time of last contact. The treatments included antibiotics, drugs to relieve pain (analgesics), drugs to reduce inflammation (corticosteroids) and **hyaluronidase** (a medicine to help break down the *Restylane® Lyft with **Lidocaine*** so that it is more easily absorbed).
- Serious allergic reactions (hypersensitivity) were reported in most cases with a time to onset ranging from immediately to few weeks post injection. Most of the events were recovered or recovering at the time of last contact. The treatments included drugs to relieve pain (analgesics), drugs to relieve allergy symptoms (antihistamines), antibiotics, and drugs to reduce inflammation (corticosteroids).
- Serious small area of inflammation in tissue (granuloma), including hardening, were reported with a time to onset ranging from one day to a year or longer. The outcomes were mostly recovered or recovering at the time of last contact. Treatment included drugs to relieve pain (analgesics), drugs to relieve allergy symptoms (antihistamines,) antibiotics, drugs to reduce inflammation (corticosteroids) and surgical removal (excisions). Incisions to examine tissue (biopsies) have been taken in some cases, but the majority of cases are non-biopsy confirmed.
- Serious inflammation was reported with a time to onset from one to two weeks post injection. Most events were recovered or recovering at the time of last contact. Rare cases of inflammation with delayed onset up to several weeks or months post injection has been observed; particularly if the patient experienced local trauma, facial/dental infection, or local infection. The treatment included drugs to relieve pain (analgesics), antibiotics, and corticosteroids.
- Blockage of a blood vessel (vascular occlusion) resulting in restricted blood flow and vision disturbances including blindness have been reported following injection of any soft tissue filler in the face especially in the nose, between the eyebrows (glabella), around the eyes (periorbital areas), smile lines (nasolabial folds) and cheek, with a time to onset ranging from immediate to a few weeks following injection. This may appear as whitening of the skin (blanching), skin discoloration, death of skin (necrosis) or ulceration at the implant site or in the area supplied by the blood vessels affected; or rarely as restriction in blood supply to tissues (ischemic events) in other organs due to blocked blood vessels (embolization). Isolated rare cases of restriction in blood supply to tissues (ischemic events) affecting the eye leading to visual loss, and the brain resulting in stroke (cerebral infarction), following facial aesthetic treatments have been reported. Reported treatments include medicine to prevent blood clotting (anticoagulant), medicine to treat allergic reactions (epinephrine), aspirin, a medicine to help break down **HA** in the body (**hyaluronidase**), drugs to reduce inflammation (corticosteroid

treatment), drugs to relieve pain (analgesics), antibiotics, local wound care, drainage, hyperbaric oxygen and surgery. Outcome of the events ranged from resolved to ongoing at the time of last contact.

- Gel injection site bruising, swelling, skin redness and pain mostly non-serious generally occurred on the same day as treatment usually resolving within 1 to 4 weeks. Some occurrences have persisted for up to 6 months. Most instances of discoloration including darkening skin tone (hyperpigmentation), sometimes described as a blue or brown color, 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.
- 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.
- Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

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
    - **NSAID** 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 or hands 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 in the face and 3.0 mL per hand.

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.
- After receiving treatment in the hands, avoid strenuous use of your hands as it may increase the risk for delayed onset adverse events.

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

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