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Restylane[®] *Silk*

Patient Brochure

Medicis (logo)

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Restylane Silk Injectable Gel with 0.3% Lidocaine

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About *Restylane Silk*

Q What is *Restylane Silk*?

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

Q How does *Restylane Silk* work?

A *Restylane Silk* is injected into the skin with an ultrafine needle to plump the skin to smooth away wrinkles and folds, such as the lines around your mouth (perioral rhytids) or into your lips for patients over the age of 21 for lip enhancement.

Q How long does *Restylane Silk* last?

A *Restylane Silk* effects generally last at least six months and gradually disappears from the body.

Q Has *Restylane Silk* been studied?

A A clinical study was conducted with *Restylane Silk* to evaluate the safety and effectiveness of injections to enhance lip fullness and to improve the wrinkles around the lips. The study included 221 mostly female subjects and evaluated subjects with light and dark skin. Subjects with very dark skin were not studied.

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Ninety-eight percent (98%) of subjects reported improvement in their lip fullness 14 days after injection and 76% of the subjects still had lip improvement 6 months after their injection. Please see the table below for additional information.

Time after injection	Subjects with improvement in lip fullness	
	No.	%
2 weeks	169/173	97.7
4 weeks	164/172	95.3
8 weeks	155/172	90.1
12 weeks	147/168	87.5
16 weeks	131/165	79.4
20 weeks	124/162	76.5
24 weeks	121/160	75.6

Improvement in the wrinkles around the lips was also seen by the treating doctor for those subjects who were seeking treatment for improvement of wrinkles. See the table below for more information.

Time after injection	Subjects with improvement in wrinkles around the lips	
	No.	%
2 weeks	49/63	77.8
4 weeks	46/63	73.0
8 weeks	44/61	72.1
12 weeks	45/62	72.6
16 weeks	41/61	67.2
20 weeks	38/59	64.4
24 weeks	38/59	64.4

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Safety

Q Who should not use *Restylane Silk*?

A *Restylane Silk* should not be used in people who are:

- Highly allergic (for example: a history of severe allergic reaction or multiple severe allergies)
- Allergic to gram positive bacteria
- Prone to bleeding disorders
- With previous hypersensitivity to local anesthetics of the amide type, such as lidocaine

Safety has not been established in people who are:

- Pregnant
- Breast feeding
- Wishing to become pregnant
- Under the age of 22 years or over 65 years

Restylane Silk should only be used to be injected into the lips and wrinkles around the lips. It should not be used in other parts of the face and body.

Q What are some warnings to consider?

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

You may experience skin bruising, swelling, pain, 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 Silk* injection.

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

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

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Q What are some potential risks you may encounter?

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

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

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

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

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

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

Bruising, redness, swelling, pain, tenderness and itching as tolerable, affecting daily activity, or disabling. When these events were reported by subjects, the majority were tolerable and most resolved within two weeks.

The events that happened most often in subjects in the clinical study after the first injection of *Restylane Silk* were bruising (44%), lip swelling (43%), lip pain (10%), general pain (8%), lip disorder (bumps, 5%), and headache (5%). Most of these events (85%) were mild and resolved in an average of three weeks. In some subjects, lip swelling started more than three weeks (up to 20 weeks) after treatment. There was no increase in the number of events when subjects received a second treatment 6 months later.

In the clinical study for *Restylane Silk* that included 61 subjects under the age of 36 and 160 subjects over the age of 35 the incidence of injection site reactions was similar in younger patients compared to older patients. The majority of these events were mild in nature.

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Post Marketing Surveillance

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

A: The adverse events received from post-marketing surveillance for the use of *Restylane Silk* when used outside the US for lip augmentation were infrequent and included mostly reports of swelling of the lip. Post-marketing reports for the use of *Restylane Silk* for all indications, including lip augmentation, occurring at the implant site in more than one patient included (in order of decreasing frequency reported) swelling, pain/tenderness, inflammation, mass/induration, erythema, and papules/nodules, infection/abscess, bruising/bleeding, non-dermatological events, and discoloration. Rarely, vision abnormalities including blindness have been reported when cosmetic facial fillers such as hyaluronic acid are used in areas around the eyes, nose and glabella.

About The Procedure

Q What are the serious side effects?

A 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 the 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.

Rarely, vision abnormalities have been reported after treatment with Restylane Silk.

Q What should patients do prior to treatment?

A *Restylane Silk* 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. Discuss with your doctor if you are on blood thinners as these may increase chance of bruising /bleeding or if you are on immunosuppressive therapy as this may increase the risk of infections. 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 Silk*?

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.

Larger amounts of injection into the lips may increase your chances of experiencing side effects.

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

Q Do the injections hurt?

A *Restylane Silk* 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 Silk* treatment cost?

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

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

A Please observe the following after treatment with *Restylane Silk*:

- 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 cold or 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.

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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 Silk* can be personally answered by contacting the Medicis toll-free call center between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, Monday through Friday.

1-800-321-4576

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