

Restylane[®]

Patient Brochure

Restylane[®]

Injectable Gel

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Frequently Asked Questions

Q What is *Restylane*?

A *Restylane* is a crystal clear injectable gel composed of hyaluronic acid, a natural substance that already exists in the body. *Restylane* is nonanimal based and free from animal protein. Allergy pretesting is not necessary.

Q How does *Restylane* work?

A *Restylane* 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 How long does *Restylane* last?

A *Restylane* effects generally last at least six months and gradually disappears from the body. If you are treated again at 4 ½ or 9 months after your first treatment, *Restylane* can last up to 18 months in the nasolabial folds. In the lips *Restylane* generally lasts six months.

Q Has *Restylane* been studied?

A *Restylane* has been studied in facial wrinkles and folds, such as the lines from your nose to the corners of your mouth (nasolabial folds), and in the lips. The studies show that *Restylane* effects generally last at least six months and gradually disappears from the body. If you are treated again at 4 ½ or 9 months after your first treatment, *Restylane* can last up to 18 months in the nasolabial folds.

Safety

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

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

- Pregnant
- Breast feeding
- Wishing to be pregnant
- Under 21 years for lip enhancement
- Under 18 years or over 65 years
- Highly allergic (for example: gram positive bacteria)
- Prone to bleeding disorders

Q What are some warnings to consider?

A The use of *Restylane* at sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of *Restylane* 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* injection.

Inflammatory papules (red or swollen small bumps) 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* 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* carries a risk of infection and formation of scar tissue.

The safety and effectiveness of *Restylane* has not been established in pregnant, or nursing mothers, and in patients under 18 or over 65 years of age. *Restylane* use in nursing could harm you or the nursing child. *Restylane* should not be used for lip enhancement in patients under the age of 21.

The use of *Restylane* in African-American patients can result in hyperpigmentation (darkening of skin color), 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* used with other skin therapies such as laser, mechanical or chemical peeling, and hair removal has not been established. The use of *Restylane* with these skin therapies may lead to other side effects such as inflammation.

You should avoid exposing the area(s) treated with *Restylane* 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:

Bruising, redness, swelling, pain (includes burning), tenderness, and itching. Most of these symptoms were considered tolerable and resolved in one to two weeks.

Q What are some benefits from clinical evaluations?

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.

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.

Q What should patients do prior to treatment?

A *Restylane* 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. 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 Do the injections hurt?

A *Restylane* 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* treatment cost?

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

Troubleshooting

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

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 redness, tenderness, and pain that does not go away you should call your doctor.

Administration

Q What is the dose of *Restylane*?

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.

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 hypersensitivity (abnormal sensitivity), vascular accidents (injury to blood supply), necrosis (death of tissue) and infection/abscess. Hypersensitivity reactions occurred within 1 to 2 days of implantation and up to 3 weeks and some required hospitalization. Reported symptoms included swelling; itching on chest and back; puffy, burning, watery, and itchy eyes; and shortness of breath. 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.

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

Is there a post-treatment checklist to follow after a *Restylane* treatment?

Please observe the following after treatment with *Restylane*:

- 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 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 (sun lamp 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.

Restylane®

User Assistance Information

Your questions about *Restylane* 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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