

Restylane®

Patient Brochure

Restylane®
Injectable Gel

Table of Contents

Frequently Asked Questions
Safety
Troubleshooting
Administration
Post Marketing Surveillance
Post-treatment Checklist
User Assistance Information

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 your lips.

Q How long does *Restylane®* last?

A *Restylane®* effects generally last 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.

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.

Safety

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

A Safety has not been established for use in people who are:

- Pregnant
- Breast feeding
- Wishing to be pregnant
- 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 less than seven days. 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.

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.

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 less than a week.

Q What are the major 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.

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 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.

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 a week. 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.

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>).

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.

Post Marketing Surveillance

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

A The adverse events received from post-marketing surveillance (voluntary reporting and published literature) for *Restylane* with and without lidocaine in the U.S. and other countries included: swelling and inflammatory reactions – immediate onset and onset up to several weeks after treatment, mass formation including lumps or bumps, induration (hardening), lack of effect, erythema (skin redness), hematoma (bruising), pain or tenderness, papules or nodules (small bumps), hyperpigmentation (skin discoloration), presumptive bacterial infections and abscess formation, inflammation, ischemia and necrosis (restricted blood flow leading to the death of skin) due to unintentional injection into a blood vessel, hypersensitivity, angioedema (swelling just below the skin), injection site reactions including burning sensation, warmth, irritation, extrusion of device, neurological symptoms including hypoaesthesia (reduced sense of touch), paraesthesia (tingling sensation), facial nerve paralysis, pruritus (itching), atrophy/scarring, visual disturbance including blurred vision lasting for a short time, reduced vision, increased flow of tears, eyelid drooping, blindness, symptoms of reactivation of herpes infection, granuloma (mass formation), device dislocation, telangiectasia (spider veins/broken capillaries), rash, blisters/vesicles, acne,

fistula, effusion/discharge, dermatitis, urticaria (hives), muscle twitching, dermatophytosis (fungal infection), encapsulation, fainting (vasovagal reactions) and other dermatological events including dry skin, skin exfoliation, skin wrinkling, alopecia (baldness), chapped lips, and non-dermatological events including headache, fever, dizziness, sinusitis, dyspnoea (shortness of breath) and anxiety.

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.

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 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

Company logo

Restylane and Galderma are registered trademarks of Nestlé Skin Health S.A.

XXXXXXXX (*Part Number for the artwork*)

Revised (MM / YYYY)