

Perlano[®]

**Frequently
Asked
Questions**



Perlane®

Efficacy

Q What is *Perlane*® used for?

A *Perlane*® is used to smooth moderate to severe facial folds and wrinkles such as the lines from the nose to the corners of the mouth (nasolabial folds). *Perlane*® generally lasts for about 6 months. It has been found to be a safe dermal filler that restores volume and fullness to the skin.

Q How does *Perlane*® work?

A *Perlane*® is injected into the skin with an ultra-fine needle. It plumps the skin to smooth away wrinkles and folds. *Perlane*®'s water-loving nature attracts and binds water molecules to help maintain volume.

Perlane® is composed of hyaluronic acid, a natural substance that already exists in the body. The hyaluronic acid in *Perlane*® is a crystal clear gel that is chemically cross-linked (the long chemical strands are tied together) to delay breakdown by skin enzymes. *Perlane*® is nonanimal-based and free from animal protein. This quality prevents disease transmission. Allergy pretesting is not necessary.

Typical results with *Perlane*.®



Before treatment
of Nasolabial folds

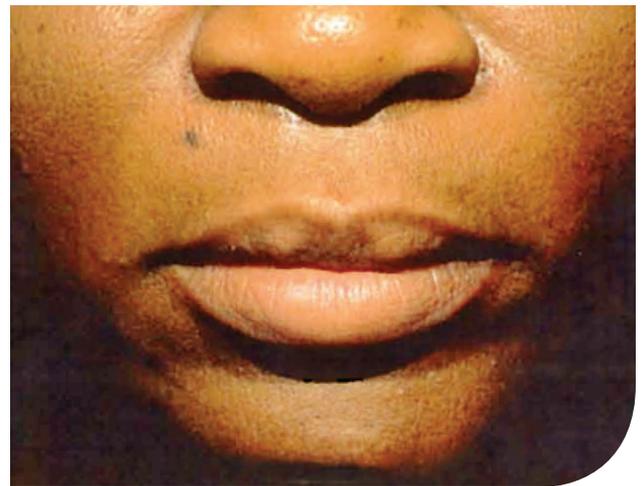


After treatment
Individual results may vary.

Typical results with *Perlane*.®



Before treatment
of Nasolabial folds



After treatment
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Typical results with *Perlane*®



Before treatment
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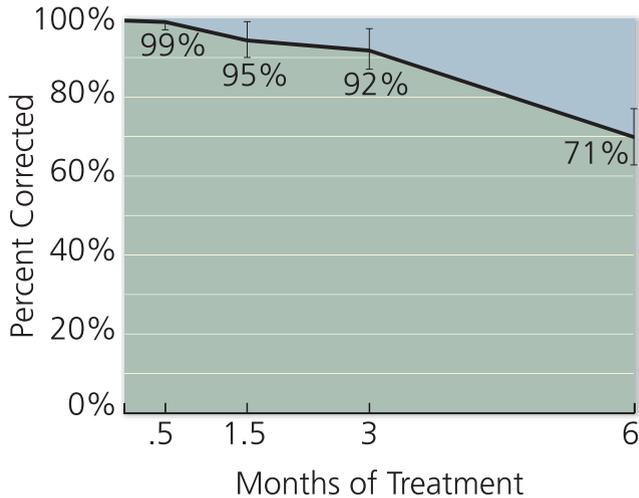


After treatment
Individual results may vary.

Q How long does *Perlane*® last?

A *Perlane*® is proven to deliver long-lasting results. Studies have shown that *Perlane*® effects generally last about six months as shown in the following graphs. *Perlane*® gradually disappears from the body without a trace.

Perlane® duration of efficacy (MA-1400-01)

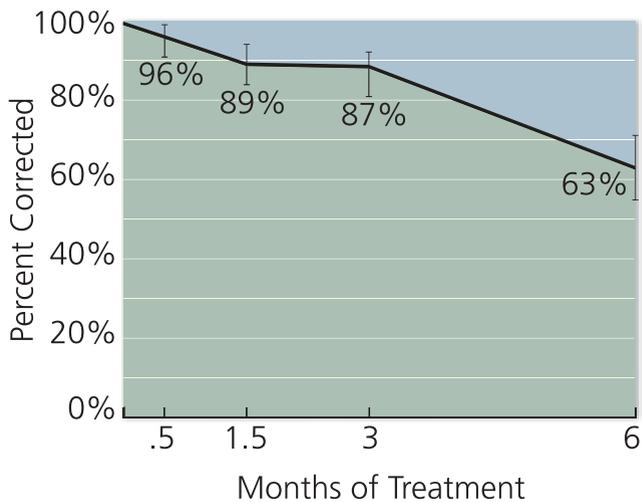


Error bars represent confidence intervals.

Summary of results

Perlane® was studied in multiple clinical studies. In one, treatment of the nasolabial folds with *Perlane*® resulted in an improvement in wrinkles in 137 of 149 patients after three months, and 105 of 148 patients after six months. In another study, treatment of nasolabial folds with *Perlane*® resulted in an improvement in wrinkles in 122 of 141 patients after three months, and 88 of 138 patients after six months. Side effects were mild. Most of the side effects went away in seven days. *Perlane*® did not cause allergic reactions. See the patient diary information on page 12.

Perlane® duration of efficacy (MA-1400-02)



Error bars represent confidence intervals.

Safety

Perlane® has been used safely by dermatologists and plastic surgeons since 2000 worldwide.

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

A *Perlane*® should not be used by people with previous bad allergies (particularly to certain microorganisms known as gram positive bacteria), to drugs that have required in-hospital treatment, or in people with bleeding disorders. *Perlane*® should not be injected anywhere except the skin or just under the skin.

Q What are some warnings to consider?

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

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

Q What are some risks that may be experienced?

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

The safety and effectiveness of *Perlane*® have not been established in the treatment of lips, in nursing mothers, and in patients under 18 or over 65 years of age. *Perlane*® use in nursing could harm you or the nursing child.

The use of *Perlane*® in African-American patients can result in hyperpigmentation (darkening of skin color), which may take several weeks to correct.

If you have had herpes before, an injection can cause the herpes to come back.

The safety of *Perlane*® used with other skin therapies such as laser, mechanical or chemical peeling, and hair removal has not been established. The use of *Perlane*® in these skin therapies may not work or they may damage your skin.

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

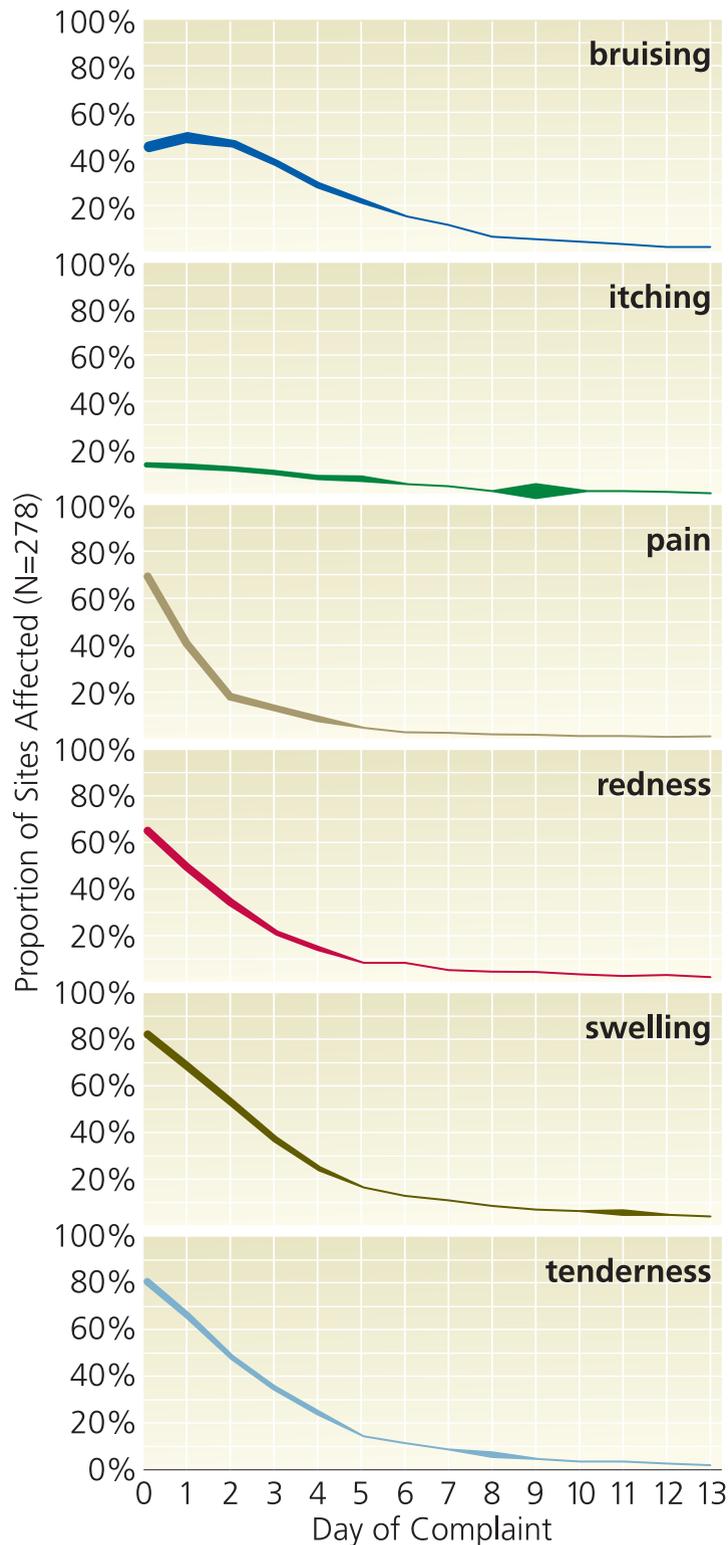
These six graphs show what happened to patients each day after an injection of *Perlane*® as shown in diaries that they kept. They explain how many patients each day experienced pain (brown line), swelling (dark green line), redness (red line), tenderness (light blue line), bruising (dark blue line), and itching (green line). The lines go down with time because fewer and fewer patients reported these effects. The thickness of the line gives an indication of how bad the effect was—the thicker the line, the more patients thought the effect was not easily tolerable. The lines generally become thinner as time goes on, meaning that the effect becomes easier to live with over time.

All these events are worsened by rapid injection and other injection techniques that cause greater disruption of the skin. Injecting large amounts of *Perlane*® also increases these events.

Percent (%) Tolerable

- 100% Tolerable
- 90% Tolerable
- 80% Tolerable
- 70% Tolerable
- 60% Tolerable
- 50% Tolerable

Where lines on the graph are thicker the symptoms are less tolerable. Thinner lines represent greater tolerability.



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 of the gel that must be treated with antibiotics or other treatment. Infection of the gel may be hard to treat, but will always go away when the gel is absorbed.

Q What should patients do prior to treatment?

A *Perlance*® 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 recurrence.

Q Do the injections hurt?

A *Perlance*® 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 do *Perlance*® treatments cost?

A *Perlance*® is a customized procedure based on your specific needs, so the cost will vary from patient to patient. In general, the cost of *Perlance*® is comparable to the cost of similar procedures. Because *Perlance*® is long lasting, it may prove to be very economical over the long term. 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 may signal that you are having a recurrent herpes infection that should 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 *Perlane*®?

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 corrected will use less than half of a tablespoon.

Post-Treatment Checklist

Please observe the following after treatment with *Perlane*[®]:

- 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 medications that may minimize a recurrence.
- 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.

Perlane®

User Assistance Information

Your questions about *Perlane*® can be personally answered by contacting the Medicis Aesthetics Inc. toll-free call center, 24 hours per day, 7 days per week.

1-800-900-6389



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PPI99810-08B Revised 01/2009