Perlane®-L

Patient Brochure

Perlane®-L

Injectable Gel with 0.3% Lidocaine

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Frequently Asked Questions

Q What is *Perlane*®-L?

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

Q How does *Perlane*®-L work?

A *Perlane*®-L 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)

Q How long does *Perlane*®-L last?

A *Perlane*®-L effects generally last about six months and gradually disappears from the body.

Q Has *Perlane*®-L been studied?

A A clinical study was conducted with *Perlane*®-L to evaluate the pain reducing effect up to 60 minutes after injection. This study enrolled 60 patients with moderate to severe nasolabial fold wrinkles. The study included 56 female patients and 4 male; 39 were White, 16 were Hispanic or Latino, and 5 were African-American.

In this study 95% of patients experienced less pain after injection of *Perlane*®-L than with *Perlane*® alone. Please see the below table for additional information.

Timepoint	Number of patients with assessments	Number of patients with pain reduction	
		No.	%
After Injection	60	57	95.0
15 Minutes	60	34	56.7
30 Minutes	60	24	40.0
45 Minutes	60	11	18.3
60 Minutes	60	5	8.3

In addition to evaluating the pain reducing effects, the study assessed patient satisfaction with *Perlane*®-L treatment. All 60 subjects were asked to rate the level of improvement seen in their nasolabial folds after injection with *Perlane*®-L. At day fourteen after injection 95.0% saw some improvement (Improved, Much Improved, and Very Much Improved). See below table for additional details.

Category	*Perlane*-L	
	n	%
Very Much Improved (4)	24	40.0
Much Improved (3)	18	30.0
Improved (2)	15	25.0
No Change (1)	3	5.0
Worse (0)	0	0.0

Safety

Q Who should not use *Perlane*®-L (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 *Perlane*®-L at sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of *Perlane*®-L 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*®-L 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 *Perlane*®-L carries a risk of infection and formation of scar tissue.

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

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

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

Perlane®-L was evaluated in a clinical study of 60 patients. The below table shows what patients reported each day after injection of *Perlane*®-L in the diary they kept. The most common events were: pain, swelling, redness, tenderness, bruising, itching and other. The reporting of these events decreased over time and by day 14 most events had resolved.

Duration of Adverse Events after Initial Treatment, Patient Diary					
	Perlane-L	*Perlane*-L Patients			
	Total patients reporting symptoms n (%)	Number of days			
		1 n (%)	2–7 n (%)	8–13 n (%)	14 n (%)
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%)

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 *Perlane*®-L 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 Why add Lidocaine to *Perlane*®?

A Lidocaine was added to *Perlane*® to reduce pain and discomfort during and after injection.

In a clinical study, 60 patients received *Perlane*® on one side of the face and *Perlane*®-L on the other side of the face. Perl*ane*®-L had an effect on reducing pain. At the time of injection, patients rated their pain about 47 on a scale of 0 to 100 for the side of the face treated with *Perlane*®. In comparison, patients rated their pain about 15 on the same scale for the side of the face treated with *Perlane*®-L. Patients reported less pain on the side of the face treated with *Perlane*®-L up to 60 minutes after treatment.

Q Do the injections hurt?

A *Perlane*®-L 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 *Perlane*®-L treatment cost?

A *Perlane*®-L is a customized procedure based on your specific needs, so the cost will vary from patient to patient. In general, the cost of *Perlane*®-L 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.

Administration

Q What is the dose of *Perlane*®-L?

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 a tablespoon.

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 Event occurring in a frequency of 5 or greater was hypersensitivity (abnormal sensitivity). Hypersensitivity reactions occurred within 1 to 2 days of implantation and up to 3 weeks. 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 *Perlane*®-L treatment?

Please observe the following after treatment with *Perlane*®-L:

- 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.

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User Assistance Information

Your questions about *Perlane*®-L 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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