About *Restylane® Eyelight*

Before beginning your treatments, please review this important information.

1. GLOSSARY

Anesthetic – a medication (or "treatment") that reduces pain.

BDDE – 1.4-butanediol diglycidyl ether, the ingredient used to crosslink the **HA**.

Cannula – a thin hollow metal tube with a blunt tip.

Crosslinked – a process in which HA chains are connected together to form a network.

Dermal filler – a material that is injected underneath the skin to smooth a wrinkle or restore volume to an area of skin.

Hyaluronic acid (HA) – a naturally occurring sugar, found in the body that gives the skin moisture, volume and elasticity.

Hyaluronidase – an enzyme that breaks down **hyaluronic acid.**

Lidocaine – a commonly used local **anesthetic** to numb the skin, see "**anesthetic**".

Necrosis – death of living tissue (skin).

NSAID - nonsteroidal anti-inflammatory medicines, such as aspirin or ibuprofen.

Topical – a cream or ointment applied to the top of the skin, affecting only the area to which it is applied.

Touch-up – an additional injection of **dermal filler** that is usually given a short time after the initial injection. Some patients may require a **touch-up** treatment to achieve the desired result.

Under-eye Hollowing – depressed, sunken, or hollow area under the eye.

2. PRODUCT DESCRIPTION

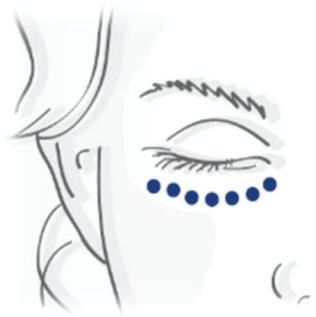
What is *Restylane® Eyelight?*

Restylane® Eyelight is a clear injectable gel composed of **hyaluronic acid (HA)**, a natural substance that already exists in the body. *Restylane® Eyelight* is **crosslinked** with **BDDE**, an ingredient that helps form a network of **HA** to provide a gel filler that lasts longer. *Restylane® Eyelight* is non-animal based and free from animal protein. *Restylane® Eyelight* contains 0.3% **lidocaine**. The **lidocaine** in *Restylane® Eyelight* is an **anesthetic** that has been added to reduce the discomfort associated with the treatment.

3. INDICATIONS FOR USE

What is *Restylane® Eyelight* for?

As you age, your facial skin begins to lose its elasticity and volume. As a result, the face droops and shifts downwards and your facial features may appear as hollow, such as the area under your eyes. *Restylane® Eyelight* injectable gel is designed to temporarily restore volume to the hollows under the eyes in patients over the age of 21. *Restylane® Eyelight* is intended for patients that are beginning to see a hollow appearance under the eyes. *Restylane® Eyelight* has been shown to maintain this effect for up to 12 months.



How is *Restylane® Eyelight* used?

Restylane® Eyelight is injected with an ultrafine needle or **cannula** under your facial skin.

4. CONTRAINDICATIONS

Are there any reasons why I should not receive *Restylane® Eyelight*?

Before using *Restylane® Eyelight*, your doctor will talk to you about your medical history to determine if you are an appropriate candidate for treatment. You will be asked questions about possible allergies to ensure that *Restylane® Eyelight* can be safely administered. Tell your doctor about all your medical conditions, including if you:

- Have severe allergies with a history of severe reactions (anaphylaxis) or multiple severe allergies.
- Have an allergy to the **lidocaine.**
- Have an allergy to any of the proteins used to make the HA in *Restylane® Eyelight*.

If you are not sure about your medical history concerning these allergies or other medical conditions you think might be relevant, please discuss further with your doctor.

5. WARNINGS

What warnings should my DOCTOR advise me about?

To help you understand the treatment risks, your doctor should discuss the following:

- One of the risks with using this product is the 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.

- The use of *Restylane® Eyelight* where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of *Restylane® Eyelight* where these are present could delay healing or make your skin problems worse.

- Tell your doctor if you have a bleeding disorder or are taking any medication that can thin your blood or prolong bleeding, such as aspirin and warfarin. As with any injection procedure this may increase your risk of bruising or bleeding at the injection site.

After having the injection, seek immediate medical attention 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.

6. PRECAUTIONS

What precautions should my doctor discuss with me?

The following are important treatment considerations for you to discuss with your doctor and understand to help avoid unsatisfactory results and complications.

- *Restylane® Eyelight* should be injected only into the **undereye hollow** area by doctors who have completed necessary training for this injection area.

- You should discuss the potential treatment risks and benefits including post treatment care considerations with your doctor.

- *Restylane® Eyelight* is only to be used for adults over the age of 21.

- Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. The safety of *Restylane® Eyelight* has not been studied in women who are pregnant or breastfeeding.

- Tell your doctor if you are taking any medications used to decrease the body's natural defense system (immunosuppressants). This may lead to an increased risk of infection.

- Tell your doctor if you have a wound healing disorder or a history of excessive scarring, particularly thick and stiff scars, or any skin color (pigmentation) disorders. Scarring and skin color changes can occur with injectable dermal fillers in general.

- Tell your doctor if you have recently had skin therapies such as laser treatment, mechanical or chemical peels or hair removal. This may lead to increased risk of side effects such as redness, swelling, heat or pain of the skin.

- Tell your doctor if you have permanent implants close to the **undereye hollow** or other prior implants, as this could increase the risk of side effects or interfere with the aesthetic outcome of the treatment.

- If you have had cold sores in the past, there is a risk that they will return after your procedure with *Restylane® Eyelight.*

- You have a dental block or use **topical lidocaine** at the same time as the filler treatment. High doses of **lidocaine** could cause a toxic reaction.

If you have any additional questions about any topic in this section, please discuss further with your doctor. See also Section 14 on when you should contact your doctor immediately after treatment.

7. CLINICAL STUDIES

How was *Restylane® Eyelight* studied?

Restylane® Eyelight was tested to ensure that it worked properly (was effective) and was safe to use in a clinical study in which 284 subjects received treatment of the hollows under the eyes. The study consisted of participants aged 22-73 years old, with approximately 80% of participants aged 30-59 years old, and 88% being female. The study included a diverse population of races (89% White, 6% Black or African American, 2% were Asian, <1% Native Hawaiian or other Pacific Islander, and 3% identified as "Other") and skin types. Skin types are described using the Fitzpatrick Skin Type (FST) Scale, which categorizes how a person's skin will react to being exposed to sunlight. Participants in the study spanned all 6 FSTs (2% Type I (skin always burns and never tans), 26% Type II (skin burns easily and tans minimally), 41% Type III (skin burns moderately and tans gradually), 22% Type IV (skin rarely burns and tans easily), 5% Type V (skin rarely burns and tans very easily), and 5% Type VI (skin never burns and tans very easily)). The BMI of participants ranged from 17.5 to 46.3, with 50% having a BMI above or below 24.4 , and 78% of all study participants were of non-Hispanic or Latino descent. To achieve subjects' desirable results, a **touch-up** treatment was allowed 1 month after the initial treatment. After 12 months, the subjects were offered an optional repeated treatment.

To evaluate the safety of *Restylane® Eyelight*, each patient kept a daily diary for 28 days after every treatment to record common side effects. Side effects were also reported by doctors based on office visits with each subject. These office visits included discussing any symptoms or complaints with the subjects and assessing the appearance of their **under-eye hollowing**. To evaluate the effectiveness of the product for the treatment

of **under-eye hollowing** a validated 4-grade photographic assessment scale was used.

8. BENEFITS

What will *Restylane® Eyelight* do for me?

Restylane® Eyelight will add volume to the hollows under your eyes to improve the appearance of the **under-eye hollowing**. The clinical study showed that the improvement lasted through 12 months, for the majority of the subjects.

The study doctors reported:

- 87% of the subjects had at least a 1-point improvement in their under-eye hollows at 3 months after treatment
- 64% of the subjects had at least a 1-point improvement in their under-eye hollows at 12 months after treatment

The subjects reported:

- 95% of the subjects rated improvement in overall appearance at 3 months and 80% at 12 months after treatment.
- The majority of the subjects responded to be satisfied or very satisfied across several distinct questions in a Subject Satisfaction Questionnaire throughout the study (range 59% to 87%). For their overall improved appearance, the subjects rated high satisfaction throughout the study between 76% to 83%.
- Subject treated with needle felt comfortable returning to social engagement (work or private) within less than 4 hours and subjects treated with cannula felt comfortable returning to social engagement within less than 12 hours after each treatment.

The effectiveness for under the eye-hollows determined by the study doctor by different subgroups at 3 months were analyzed and are presented in Table 1. The differences between subgroups are minor and not statistically significant.

Table 1: Effectiveness of Restylane Eyelight with improvement in under the eye-hollows at 3 months per subgroup

Subgroup		Treated subjects with improvement in under the eye-hollows at 3 months (%)
Sex	Female	89% (197/221)
	Male	94% (32/34)
Age category	22-29	94% (29/31)

	30-44	96% (91/95)
	45-59	83% (89/107)
	60-73	91% (20/22)
Fitzpatrick Skin Type	I - III	90% (157/174)
	IV - VI	89% (72/81)
Injection tool	Needle	92.9% (118/127)
	Cannula	86.7% (111/128)

9. RISKS

What are possible side effects?

In the study of *Restylane® Eyelight* to restore volume to the hollows under the eyes, most subjects reported the following reactions at the site where they received the injection, see Table 2:

Table 2: Reactions Reported by Patients After Initial Injection

Temporary reactions after Initial Injection (N=301)	**Total (%)**
Pain (including burning sensation)	180 (60)
Tenderness	270 (90)
Redness (erythema)	185 (61)
Bruising	190 (63)
Swelling	256 (85)
Lumps/Bumps (papules/nodules)	161 (53)
Itching (pruritus)	43 (14)

For most patients, these temporary reactions occurred immediately up to two days after the injection, were mild and resolved within 7 days or less. Up to 36% of the patients had a temporary reaction that lasted more than 7 days, see Table 3

Table 3: Duration of Patient-Reported Injection Site Reactions

After Initial Injection (N=288)	1 Day	2 – 7 Days	8 – 13 Days	14 – 28 Days
Pain (including burning)	67 (37)	105 (58)	8 (4)	0
Tenderness	30 (11)	201 (74)	30 (11)	9 (3)
Redness	44 (24)	129 (70)	9 (5)	3 (2)
Bruising	24 (13)	105 (55)	45 (24)	16 (8)
Swelling	30 (12)	196 (77)	25 (10)	5 (2)
Lumps/Bumps	29 (18)	78 (48)	23 (14)	31 (19)
Itching	19 (44)	24 (56)	0	0

Side effects reported by doctors on the study that were considered to be related to *Restylane® Eyelight* included swelling (edema), implant site pain, headache, implant site bruising, mass formation/hardening . Out of 316 total subject treated with the device in the study, 40 subjects experienced these side effects.

Of the 40 subjects that experienced side effects, cannula was used to inject *Restylane® Eyelight* in 32 (80%) subjects whereas needle was used to inject *Restylane® Eyelight* in 8 (20%) subjects. Females and subjects with BMI less than or equal to 24.25 experienced more related side effects, see Table 4: Related Side Effect per sex and BMI subgroups

Subgroup		Subjects with related AEs after initial treatment including touch-up treatment (%, n/N)
Sex	Female (N=276)	40 (14.5%)
	Male (N=40)	3 (7.5%)
Body Mass Index (BMI)	BMI <= 24.25 (N=154)	28 (18.2%)
	BMI > 24.25 (N=161)	15 (9.3%)

. A higher percentage of subjects experienced related side effects if they got local injection of anesthetics before treatment to reduce discomfort compared with subjects who received anesthetics on the skin, 21% and 10%, respectively.

Table 4: Related Side Effect per sex and BMI subgroups

Subgroup		Subjects with related AEs after initial treatment including touch-up treatment (%, n/N)
Sex	Female (N=276)	40 (14.5%)

	Male (N=40)	3 (7.5%)
Body Mass Index (BMI)	BMI <= 24.25 (N=154)	28 (18.2%)
	BMI > 24.25 (N=161)	15 (9.3%)

Vision was evaluated in the study. Six % (6) of the subjects who received treatment had a worsening in vision during the study. All events were mild, and not considered related to *Restylane® Eyelight* or the injection procedure.

Apart from the above-mentioned side effects, other common reported side effects from use of *Restylane® Eyelight* include:

- temporary swelling (edema) and inflammatory reactions with immediate onset or delayed onset, up to several weeks after treatment
- redness (erythema)
- pain/tenderness
- lumps/bumps (papules/nodules)
- uneven appearance of the skin (deformity/asymmetry)
- short duration of effect
- presumptive bacterial infections/pockets of pus (abscess)
- Skin reactions at the injection location including dryness, discomfort, exfoliation, irritation and warmth
- eye disorders such as dry eye, eye swelling, increased tear flow (increased lacrimation), eyelid drooping (eyelid ptosis), and reduced vision including blurred vision and blindness,
- allergic reaction (hypersensitivity),
- itching (pruritus),
- scarring,
- restricted blood flow (ischemia/necrosis)
- small area of inflammation in tissue (granuloma)
- implanted gel moving from site of injection (device dislocation)
- rash,
- leakage of product (discharge),
- hives (urticaria),
- blisters,
- skin irritation (dermatitis),
- acne,
- muscle twitching and muscle weakness,
- encapsulation,
- symptoms of reactivation of herpes infection like cold sores,
- fungal infection of the skin (dermatophytosis),
- other local side effects, including dry skin and skin wrinkling

- other side effects not associated with the treatment location including feeling sick (malaise), fever (pyrexia), sinusitis

Rarely, the doctor may accidentally inject the product into a blood vessel, which can cause injury to the blood supply. 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 death of tissue (skin **necrosis**) with temporary scabs, permanent scarring of the skin or vision changes (including blindness), stroke. Please contact your doctor immediately if you experience these symptoms, see section 14 When to call your doctor.

Although most side effects will resolve with time, some side effects may persist longer than 30 days. Your doctor may choose to treat them with medications, such as antibiotics, drugs to reduce inflammation (corticosteroids), drugs to relieve pain (analgesics), drugs to relieve allergy symptoms (antihistamines), local drugs that widen blood vessels, surgical procedure (drainage) or **hyaluronidase** (an enzyme that breaks down **HA**).

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

If you have any questions concerning possible side effects, please discuss further with your doctor. You should always tell your doctor if you experience anything unusual at the site of treatment.
See Section 14 for additional information on when you should contact your doctor immediately.

10. BEFORE PROCEDURE INFORMATION

What happens in the office before the injection?

Note that each doctor may have a unique process for treating patients.

The following is an example of what your doctor may do before the injection procedure:

- Talk to you about your medical history, including questions about prior procedures, surgeries, illnesses and medications you have taken.
- Talk to you about your desired results for your procedure.
- Examine your face and discuss whether *Restylane® Eyelight* is the right treatment for you.
- Review what you should expect during and after the procedure.
- Let you know of any possible side effects that you may experience, and what to do if you experience these.
- Take photos of the area of your face that will be treated.

Your doctor may also have additional ways of evaluating patients and preparing them for a procedure.

11. PROCEDURE DESCRIPTION

What happens during the procedure?

Your doctor may do the following during your procedure:

- Your skin will be cleansed prior to treatment.
- Use a cream or ointment called a **topical anesthetic** to numb the area where you will receive your injection.
- Your doctor will begin the procedure by giving you the first injection, then pausing to allow the **anesthetic** that is part of *Restylane® Eyelight* to continue to numb the area around your injection. The **anesthetic** part of *Restylane® Eyelight* has been shown to significantly reduce the pain and discomfort that may occur with a **dermal filler** gel injection.
- Your doctor will inject *Restylane® Eyelight* to achieve the desired results. The recommended dose is 1 mL per side for the infraorbital hollow area per treatment.
- After the injection is completed, your doctor may gently massage the area that was treated to ensure the **dermal filler** gel is distributed evenly and looks natural.

12. AFTER PROCEDURE INFORMATION

What should I do after receiving treatment?

- 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.
- For the first 24 hours, you should avoid or minimize hard (strenuous) exercise. You should also avoid or minimize exposure to extensive sun or extreme temperatures. Exposure to any of these may cause the area where you were treated to temporarily become red, swell and/or itch. If you experience any of these, an ice pack can be applied for relief.
- Avoid taking aspirin, **NSAID**, blood thinners, and high doses of Vitamin E supplements for one week after treatment. These agents may increase bruising and bleeding at the injection site.

13. ALTERNATIVE PROCEDURES

What other treatments are available to me?

There are other **dermal filler** gels in the United States that are available to you for treatment. Additionally, there are alternative treatments such as surgical procedures, implants or fat injections. You can discuss these treatments with your doctor to determine which one is right for you.

14. WHEN TO CALL YOUR DOCTOR

When should I call my doctor?

You should call your doctor immediately 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). (http://www.nlm.nih.gov/medlineplus/stroke.html)
- White appearance of the skin.
- Unusual pain during or shortly after treatment.

Be sure to call your doctor if you have:

- Persistent injection site reactions beyond 14 days, as most side effects such as bruising, swelling, pain, tenderness, redness, and itching will usually go away within one to two weeks.
- Blisters or skin sores that recur, which may signal the presence of a herpes infection.
- Any signs of infection such as fever, redness that spreads to surrounding areas, drainage, increasing tenderness or increasing pain that does not go away.
- Significant pain away from the injection site.
- Any side effect that occurs weeks or months after treatment.
- Any other symptoms that cause you concern.

15. ADDITIONAL INFORMATION

What if I experience a problem?

If you believe that you have experienced a serious problem related to *Restylane® Eyelight* you should call your doctor. Your questions about *Restylane® Eyelight* 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

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