

## About Restylane® Contour

Before beginning your treatments, please review this important information.

### 1. GLOSSARY

**Anesthetic** – a medication (or “treatment”) that reduces pain.

**BDDE** – the ingredient used to crosslink the **HA**.

**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**”.

**Temple hollowing** – refers to the visible depression or sunken area in the temples. This can be due to, intrinsic characteristics, the natural aging process or weight loss.

**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.

## 2. PRODUCT DESCRIPTION

### What is *Restylane Contour*?

*Restylane Contour*<sup>®</sup> is a **dermal filler** injected under the (facial) skin. Once in place, it helps restore volume of your midface. *Restylane Contour* may also be used to increase fullness of your cheeks or temples.

*Restylane Contour* is made out of **hyaluronic acid (HA)** - a naturally occurring sugar, found in the body that gives the skin moisture, volume and elasticity – and a small amount of **lidocaine**, which is a commonly used local **anesthetic** to numb the skin. *Restylane Contour* is **crosslinked** with **BDDE**, an ingredient that helps form a network of **HA**, to provide a gel filler that lasts longer at the treatment site.

## 3. INDICATIONS FOR USE

### What is *Restylane Contour* 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 become hollow. This can also happen after weight loss.

*Restylane Contour* injectable gel is designed to temporarily restore volume to the midface and to add fullness to the cheeks in patients over the age of 21.

*Restylane Contour* is indicated for correction of **temple hollowing** in patients over the age of 21.

*Restylane Contour* has been shown to maintain treatment effect for up to 12 months when treating the midface and cheeks and up to 18 months when treating the temples.

### How is *Restylane Contour* used?

*Restylane Contour* is injected with a small needle or cannula under your facial skin.

## 4. CONTRAINDICATIONS

### Are there any reasons why I should not receive *Restylane Contour*?

Before using *Restylane Contour*, 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 Contour* 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. Use of *Restylane Contour* may result in an allergic reaction.
- Are allergic to the **anesthetic lidocaine** or to any of the proteins used to make the **HA** in *Restylane Contour* (bacterial proteins). Use may result in an allergic reaction.
- Are prone to bleeding or have been diagnosed with a bleeding disorder. An injection of *Restylane Contour* may have a higher risk of severe bleeding or bruising.

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

## 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 in order to help avoid unsatisfactory results and complications.

- You should discuss the potential treatment risks and benefits with your doctor.
- *Restylane Contour* 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 Contour* 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). *Restylane Contour* injections may then result in an increased risk of infection.
- 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.
- Tell your doctor if you have 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. When *Restylane Contour* was studied in patients with different skin tones (pale to dark), there were no reports by patients of excessive scarring (keloids) or changes in skin color.
- 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.
- If you have had cold sores in the past, there is a risk that they will return after your procedure with *Restylane Contour*.

- Avoid or minimize hard (strenuous) exercise and exposure to extensive sun, UV lamps, indoor tanning beds/booths, or extreme temperatures within the first 24 hours after treatment with *Restylane Contour*. Any of these may cause temporary redness, swelling, pain and/or itching at the injection site.
- Tell your doctor immediately if you experience any changes in your vision, signs of a stroke, white appearance of the skin, or unusual pain during or shortly after treatment. These could be signs of an unintentional intravascular injection and require immediate medical care to avoid permanent complications.

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 Contour* studied?

*Restylane Contour* was tested to ensure that it worked properly (was effective) and was safe to use in a clinical study comparing it to an approved **dermal filler** before it was approved for use in cheek augmentation and correction of midface contour deficiencies. This study included 270 patients. In addition, a second study was conducted with 225 patients to verify that *Restylane Contour* was also effective and safe for the correction of **temple hollowing**. In this second study, the results obtained after treating patients with *Restylane Contour* were compared to those obtained in the absence of any treatment.

### Study for cheek augmentation and correction of midface

Patients who participated in the first study received an initial treatment with *Restylane Contour* or another similar **dermal filler** gel. The selection of product was randomly assigned to each patient so that 202 patients received *Restylane Contour* and 68 patients received the comparator product. **Touch-up** injections were given as needed after 4 weeks with the same product as used at the initial treatment.

In Group A; 187 women and 23 men from various ethnic groups with multiple skin tones (pale to dark skin) were included. Each of these patients expressed desire to correct midface volume loss and increase fullness of the cheeks. 142 patients received treatment with *Restylane Contour* using a needle and 68 patients received the comparator product gel using a needle.

In Group B; 55 women and five men were included. All received *Restylane Contour*, about half were treated using a needle and for the other half, the doctor used a cannula.

The study was created to compare two different **dermal filler** gel products and to ensure *Restylane Contour* is effective and safe using two different injection tools; a needle and a cannula. It was conducted by 17 different doctors in 17 different locations across the United States.

Each patient was monitored for 12 months following the procedure to measure the effect of treatment. For each patient, the amount of product used was based on their individual need.

In order to objectively measure improvements in midface volume over 12 months, each patient was evaluated by a doctor other than the one who had performed the treatment. Patients also evaluated themselves. To measure side effects following the procedure, each patient kept a diary for 28 days to record side effects. These were then shared with the doctors.

After 12 months, all patients could receive an optional re-treatment with the same product as used at the initial treatment. Patients that received re-treatment were monitored for another 12 weeks for the effect and safety of repeat treatment.

### **Study for temple hollowing**

In the second study, patients received either an initial treatment with *Restylane Contour* or no treatment. The decision to treat or not to treat patients with *Restylane Contour* was made randomly. A total of 181 patients received *Restylane Contour* (Treatment group) and 44 patients did not receive any treatment (Control group). The patients in the Treatment group were given **touch-up** injections with the same product as needed 4 weeks after the initial treatment. The patients in the Control group were offered optional treatment after 3 months.

The study included 213 women and 12 men from various ethnic groups with multiple skin tones (pale to dark skin). Each of these patients expressed desire to correct **temple hollowing**. *Restylane Contour* was administered in the temple area using a needle for supraperiosteal injections and using a cannula or needle for subdermal injections. Thus, the study was designed to ensure that *Restylane Contour* is effective and safe using two different injection tools; a needle and a cannula.

The study was conducted by 15 different doctors in 15 different locations across the United States.

Improvements in temple volume were primarily evaluated 3 months after the initial treatment. In addition, patients in the Treatment group were monitored for 18 months following the initial treatment to measure the effect of treatment over time. The patients in the Control group who received the optional treatment after 3 months were monitored for 12 months after treatment. For each patient, the amount of product used was based on their individual needs.

Over the 12- or 18-month monitoring period, each patient was evaluated by the doctor who had administered the treatment and by another independent doctor. Patients also evaluated themselves. To measure side effects following the procedure, each patient kept a diary for 28 days to record side effects. These were then shared with the doctors.

## 8. BENEFITS

### *What will Restylane Contour do for me?*

*Restylane Contour* will temporarily restore volume to your midface.

*Restylane Contour* will temporarily add volume for increased fullness of your cheeks.

*Restylane Contour* will temporarily add volume to correct **hollowing** of your temples.

*Restylane Contour* was studied in many patients to determine if it was effective and to ensure that it is safe for use.

In the first study, the doctors reported:

- *Restylane Contour* and the comparator **dermal filler** have similar abilities in restoring volume to your midface and adding volume for increased fullness of the cheeks 12 weeks after initial treatment.
- 88.5% (116/131) of patients treated with *Restylane Contour* in Group A had at least a 1-point improvement in midface volume 6 months after treatment.
- In Group B, 81.8% (45/55) of patients treated with *Restylane Contour* using a cannula and 90.9% (50/55) of subjects treated with *Restylane Contour* using a needle had at least a 1-point improvement in midface volume 6 months after treatment.
- 62.8 % (81/129) of patients treated with *Restylane Contour* in Group A had at least a 1-point improvement in midface volume 12 months after treatment.

- In Group B, 61.8 % (34/55) of patients treated with *Restylane Contour* using a cannula and 65.5% (36/55) of patients treated with *Restylane Contour* using a needle had at least a 1-point improvement in midface volume 12 months after treatment.

The patients reported:

In Group A:

- 90.1% (118/131) rated an improvement in the appearance of the midface 6 months after treatment.
- 76.9% (100/130) rated an improvement in the appearance of the midface 12 months after treatment.

In Group B:

- 98.2% (54/55) rated an improvement in the appearance of the midface 6 months after treatment using a cannula and 96.4% (53/55) rated an improvement in the appearance of the midface 6 months after treatment using a needle.
- 90.7% (49/54) rated an improvement in the appearance of the midface 12 months after treatment using a cannula and 88.9% (48/54) rated an improvement in the appearance of the midface 12 months after treatment using a needle.

In the second study, the doctors reported:

- An improvement of at least 1 point in the volume of both temples 3 months after the initial treatment in 87.6% of patients treated with *Restylane Contour* using a needle for subdermal injections and in 95.7% of patients treated using a cannula for subdermal injections.
- An improvement of at least 1 point in the volume of both temples in 94.6% of patients 6 months after treatment, in 92.8% of patients 9 months after treatment, in 91.6% of patients 12 months after treatment, and in 86.1% of patients 18 months after treatment with *Restylane Contour*. Using a needle or a cannula for subdermal injections did not make any significant difference.
- An aesthetic improvement for most patients over the 12- or 18-month monitoring period after treatment (between 88.5% and 100% of patients in the Treatment group, and between 92.1% and 97.4% of patients in the Control group).

- In the Treatment group the results were natural looking for 99.4% of patients, and doctors were satisfied with how the product enabled them to correct **temple hollowing** for 97.7% of patients.

In the second study, the patients reported:

In the Treatment group (*Restylane Contour*):

- Most patients reported an aesthetic improvement over the 18-month monitoring period (between 80.6% and 96.0% of patients).
- The majority of patients would recommend the treatment to a friend (between 92.1% and 95.2% of patients) and would choose to receive the treatment again (between 90.3% and 92.2% of patients).
- Almost all patients (97.1%) were satisfied with how quickly they could go back to social engagements after treatment.

In the Control group (no-treatment followed by optional treatment at 3 months):

- Most patients reported an aesthetic improvement over the 12-month monitoring period following the optional treatment (between 81.6% and 92.3% of patients).

## 9. RISKS

### What are possible side effects?

In the studies of *Restylane Contour* to restore volume of the midface and increase fullness of the cheeks or temples, most patients reported the following side effects at the site where they received the injection:

- Redness
- Pain
- Tenderness
- Swelling
- Bruising
- Itching
- Lumps and bumps (only recorded in the second study)

For most patients, these temporary reactions occurred immediately up to two days after the injection, were mild, and disappeared within 1-2 weeks. The longest duration reported for any of these events was 28 days. The latest onset reported for any of these events was 14 days.

Other side effects reported in the studies included bleeding, small bumps and numbness at the treatment site, twitch and swelling of the eyelid, facial pain, skin sensation without stimuli, and headache.

As with all skin injection procedures, there is a risk of infection which could appear as small, swollen or red bumps or pockets of pus.

There are also other potential side effects that can occur with **dermal filler** gel injections. Apart from the above-mentioned side effects, other common reported side effects from use of *Restylane Contour* outside the US included:

- reports of temporary swelling (edema) with immediate onset or delayed onset, up to several weeks after treatment
- lumps or bumps (mass formation)/hardening (induration)
- inflammation
- restricted blood flow (ischemia/necrosis) including pale skin (pallor), netlike pattern of reddish-blue skin discoloration (livedo reticularis)
- allergic reaction (hypersensitivity)/rapid swelling (angioedema)
- skin discoloration
- reduced sense of touch (hypoesthesia), tingling sensation (paresthesia), compression of nerve and facial nerve paralysis
- small area of inflammation in tissue (granuloma)
- implanted gel moving from site of injection (device displacement)
- eye discomfort and blurred vision
- uneven appearance of the skin (asymmetry/deformity)
- symptoms of reactivation of herpes infection
- blisters/vesicles
- leakage from implant site (extrusion)
- acne
- muscle disorders such as muscle swelling
- non-dermatological events including dizziness, influenza-like symptoms such as chills, fever and discomfort, nausea, sudden attack of illness (seizure)
- other dermatological events including dry lips, and excessive sweating

Rarely, the doctor may accidentally inject the product into a blood vessel, which can cause injury to the blood supply and damage to the skin. 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 changes (including blindness), stroke, temporary scabs, or permanent scarring of the skin. 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**).

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.

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.

## 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 Contour* 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 Contour* to continue to numb the area around your injection. The **anesthetic** part of *Restylane Contour* has been shown to significantly reduce the pain and discomfort that may occur with a **dermal filler** gel injection.
- Your doctor will continue the injection of *Restylane Contour* until the area being treated shows the desired results.
- 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, St. John's Wort, 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 Contour* you should call your doctor. Your questions about *Restylane Contour* 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 to through Friday.

1-855-425-8722

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