

About Restylane® Contour

Before beginning your treatments, please review this important information.

1. GLOSSARY

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

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**”.

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

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.

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

2. PRODUCT DESCRIPTION

What is Restylane Contour?

Restylane Contour® 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.

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.

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 has been shown to maintain this effect for up to 12 months.

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.

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 13 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 all patients. This study included 270 patients.

Patients who participated in the 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.

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

The study 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.

9. RISKS

What are possible side effects?

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

- Redness
- Pain
- Tenderness
- Swelling
- Bruising
- Itching

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 study 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)
- allergic reaction (hypersensitivity)/rapid swelling (angioedema)
- reduced sense of touch (hypoesthesia), tingling sensation (paraesthesia)
- small area of inflammation in tissue (granuloma)
- implanted gel moving from site of injection (device displacement)
- uneven appearance of the skin (deformity/asymmetry)
- skin discoloration

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 13 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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Revised: June 2023