

DRAFT Patient Information Labeling

About JUVÉDERM VOLUMA® XC

Before beginning your treatments, please review this important information.

Glossary of Terms

- *Anaphylaxis* - severe allergic reaction
- *Cushioning agent* - absorbs shock
- *Global Aesthetic Improvement Scale* - a 5-point scale commonly used in dermal filler studies to measure patient satisfaction
- *Gram positive bacterial proteins* - pieces of protein from the bacteria that produce the hyaluronic acid used in JUVÉDERM®
- *Hyaluronic acid (HA)* - a polysaccharide (sugar) that occurs naturally in the body. It keeps skin moisturized and flexible. HA fillers, including the JUVÉDERM® XC range of products, are a modified form of the HA that occurs naturally in your body
- *Hyaluronidase* - an enzyme that breaks down HA
- *Hypertrophic scarring* - a thick, hard scar that can grow over an injured area
- *Inflammatory reaction* - a localized response to injury, typically including pain, heat, redness, and swelling
- *Keloid formation* - a thick, hard scar that grows beyond an injured area
- *Lidocaine* - a synthetic compound used as a local anesthetic to decrease pain
- *Mid-Face Volume Deficit Scale* - a 6-point scale used in the clinical study to measure mid-face volume loss
- *Optimal* - the best possible outcome
- *Pigmentation disorders* - a lightening or darkening of an area of the skin
- *Repeat injection* - an additional injection of dermal filler given after the effects of the treatment have worn off in order to maintain optimal correction
- *Subject* - a person participating in a clinical study
- *Topical* - cream or ointment applied to a certain area of the skin and affecting only the area to which it is applied
- *Touch-up* - an additional injection of a small amount of dermal filler given approximately 1 month after the initial injection. A touch-up treatment may be necessary to obtain an optimal outcome
- *Treatment site responses* – side effects from treatment
- *VYCROSS® technology* - a unique manufacturing process that provides a high concentration of cross-linked HA for long-lasting results. It works to create a smooth consistency gel that flows easily into the skin and provides a smooth, natural look and feel

What is it? JUVÉDERM VOLUMA® XC injectable gel is a smooth, colorless HA gel that contains a small quantity of local anesthetic (lidocaine). HA is a naturally occurring sugar found in the human body. The role of HA in the skin is to deliver nutrients, help the skin retain its natural moisture, and to act as a cushioning agent. The addition of lidocaine helps to reduce

the pain associated with injections into the skin. JUVÉDERM VOLUMA[®] XC is manufactured using VYCROSS[®] technology to give a specialized smooth-gel structure that produces long lasting results at the treatment site. JUVÉDERM VOLUMA[®] XC is delivered by an injection into the facial tissue to add volume and fullness to the cheek and surrounding areas of the mid-face region.

What does it do? As you age, your face loses volume. JUVÉDERM VOLUMA[®] XC temporarily adds volume to facial tissue and restores a smoother appearance to the face. The lidocaine in the gel improves the comfort of the injection.

How is it used? It is injected into the cheek area. It temporarily adds volume to aging skin and may give the appearance of a more youthful, smoother skin surface.

What will it accomplish? It will help to volumize the cheeks. Most patients require a touch-up treatment after their initial treatment to achieve optimal cheek volumization. Once optimal volumization is achieved, results last about 21 months.

What are possible side effects?

In the clinical study, most side effects were mild (barely noticeable) to moderate (uncomfortable) in nature, and most resolved within 2 weeks. The most common side effects include, but are not limited to, temporary treatment site reactions such as tenderness, swelling, firmness, and lumps/bumps. These side effects are consistent with other facial injection procedures.

As with all skin injection procedures, there is a risk of infection.

Although most side effects will resolve with time, your physician may choose to treat them with medications, such as antibiotics, steroids, or hyaluronidase.

**Are there any reasons why I should not receive JUVÉDERM VOLUMA[®] XC?
(Contraindications)**

Your physician will ask about your medical history to determine if you are an appropriate candidate for treatment. The product should not be used in patients who have:

- Severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies
- A history of allergies to lidocaine or gram-positive bacterial proteins

What should my physician warn me about?

The safety and effectiveness for the treatment of areas other than the cheeks have not been established in controlled clinical studies.

What precautions should my physician advise me about? The following are important treatment considerations for you to discuss with your physician and understand in order to help avoid unsatisfactory results and complications.

- The safety for use during pregnancy, in breastfeeding females, or in patients under 35 years has not been established
- The safety in patients with a history of excessive scarring (e.g., hypertrophic scarring and

- keloid formations) and pigmentation disorders has not been studied
- JUVÉDERM VOLUMA[®] XC should be used with caution in patients on immunosuppressive therapy, or therapy used to decrease the body's immune response, as there may be an increased risk of infection
 - Patients who are using substances that can prolong bleeding, such as aspirin or ibuprofen, as with any injection, may experience increased bruising or bleeding at the injection site. You should inform your physician before treatment if you are using these types of substances

What did the clinical study show?

In the U.S. clinical study 270 subjects were treated with JUVÉDERM VOLUMA[®] XC to establish the product's safety and effectiveness. Most subjects experienced tenderness, swelling, firmness, and/or lumps/bumps at the injection site. The treatment site responses were usually mild or moderate in severity, did not require intervention, and generally lasted 2 weeks or less. The percentage of subjects who reported common treatment site responses at initial and repeat treatments are shown in Tables 1 and 2 below.

Table 1
Treatment Site Responses at Initial Treatment*
N = 265**

Treatment Site Response	n	%
Any Treatment Site Response	260	98.1%
Tenderness	244	92.1%
Swelling	227	85.7%
Firmness	218	82.3%
Lumps/Bumps	215	81.1%
Bruising	206	77.7%
Pain	176	66.4%
Redness	175	66.0%
Discoloration	109	41.1%
Itching	102	38.5%

* occurring in >5% of subjects

** N is the number of subjects who provided information about treatment site responses after treatment

Table 2
Treatment Site Responses at Repeat Treatment*
N=107**

Treatment Site Response	n	%
Any Treatment Site Response	97	90.7%
Tenderness	80	74.8%
Firmness	73	68.2%
Swelling	72	67.3%
Bruising	65	60.7%
Lumps/Bumps	63	58.9%
Redness	59	55.1%
Pain	57	53.3%
Itching	36	33.6%
Discoloration	26	24.3%

* occurring in > 5% of subjects

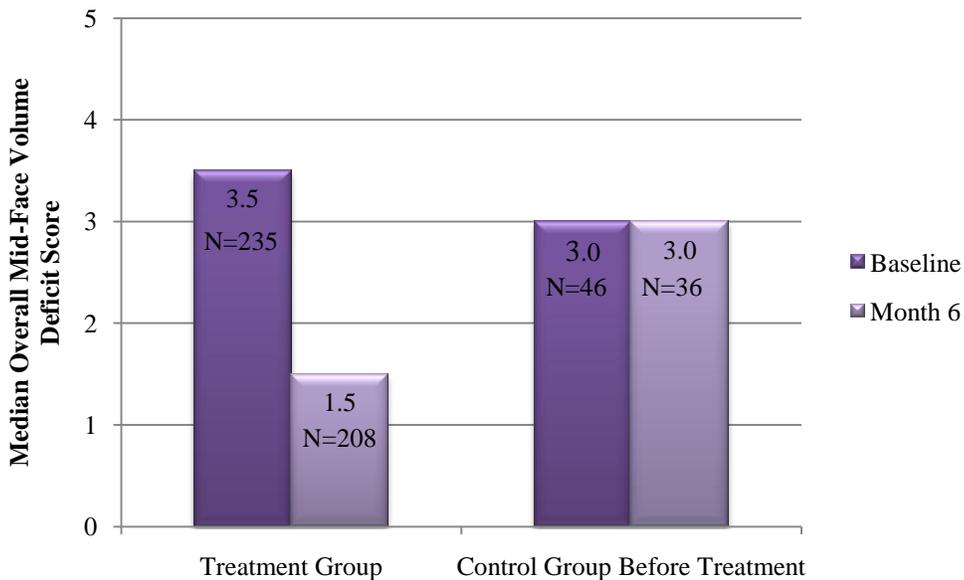
** N is the number of subjects who provided information about treatment site responses after treatment

Subjects' mid-face volume deficit was assessed on a 0 to 5 scale (Table 3). Using this 6-point mid-face volume deficit scale, JUVÉDERM VOLUMA® XC was found to effectively volumize the cheeks compared to the control group who did not receive any treatment. As shown in Figure 1, subjects had a 2-point improvement in their mid-face volume deficit score at 6 months after treatment.

Table 3
Mid-Face Volume Deficit Scale

Score	Severity
0	None
1	Minimal
2	Mild
3	Moderate
4	Significant
5	Severe

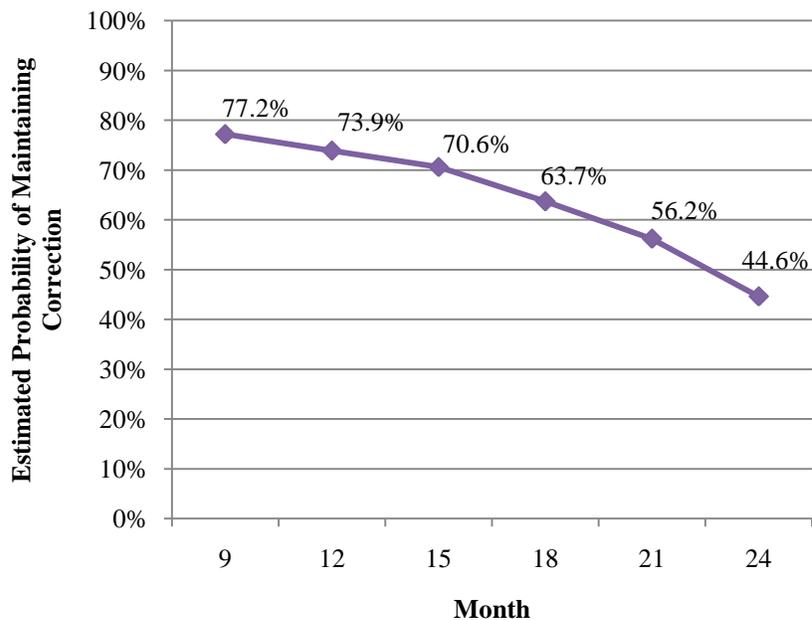
Figure 1
Overall Mid-Face Volume Deficit Score at Baseline and Month 6



At 6 months, 86% (178/208) of treatment group subjects improved by ≥ 1 point (mean improvement of 1.7 points) compared with their pre-treatment assessment and maintained an improvement of ≥ 1 (mean improvement of 1.1 points) through 24 months. In addition, subjects rated themselves as looking an average of 5 years younger at 6 months, and 3 years younger at 24 months. Additionally, 82% (171/208) of treatment group subjects improved by ≥ 1 point on the Global Aesthetic Improvement Scale compared with their pre-treatment assessment at 6 months.

Figure 2 shows the likelihood of maintaining correction between 9 and 24 months, based on the clinical study results.

Figure 2
Duration of Volumizing Effect



Do the injections hurt?

Injections may cause some discomfort during and after the injection. In the JUVÉDERM VOLUMA[®] XC clinical study, on average, subjects rated pain as a 3 on an 11-point scale where 0 is no pain and 10 is worst pain imaginable. JUVÉDERM VOLUMA[®] XC contains an anesthetic to reduce injection site pain. Physicians may choose to numb (anesthetize) the treatment area with a cream placed directly on the injection site (topical) to further minimize discomfort.

What should I expect following the procedure?

Your physician will tell you what to expect following treatment with JUVÉDERM VOLUMA[®] XC. Within the first 24 hours, you should avoid strenuous exercise, extensive sun or heat exposure, and alcoholic beverages. Exposure to any of the above may cause temporary redness, swelling, and/or itching at the injection sites. If there is swelling, you may need to place an ice pack over the swollen area. You should ask your physician when makeup may be applied after your treatment.

Does the correction last forever?

No. Correction is temporary; therefore, touch-up injections as well as repeat injections are usually needed to maintain optimal correction.

What other treatments are available to me?

Alternative treatments that are available to you to restore lost facial volume include surgical implants or injection of your own fat. You may discuss these treatments with your physician.

When should I notify my physician?

Be sure to report to your physician 1) any redness and/or visible swelling that lasts for more than a few days and 2) any other symptoms that cause you concern. You may also contact the Allergan Product Support line at 1-877-345-5372.

For further questions and information, please call Allergan 1-800-766-0171.

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