

## **JUVÉDERM™ and VOLUMA™**

### **What is it?**

JUVÉDERM™ and VOLUMA™ are a colorless hyaluronic acid gel that is injected into facial tissue to smooth wrinkles and folds and replace volume loss. Hyaluronic acid is a naturally occurring sugar found in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding in water, and to act as a cushioning agent.

### **What does it do?**

JUVÉDERM™ and VOLUMA™ temporarily adds volume to facial tissue and restores a smoother appearance to the face.

### **What will it accomplish?**

JUVÉDERM™ will help to smooth moderate to severe facial wrinkles and folds. Most patients need one treatment to achieve optimal wrinkle smoothing, and the results last about 1 year. VOLUMA™ will add volume and restore contour to the cheek area and the results last up to 2 years with optimal treatment. Often more than one syringe is necessary to achieve full correction.

### **What are possible side effects?**

Most side effects are mild or moderate in nature, and their duration is short lasting (7 days or less). The most common side effects include, but are not limited to, temporary injection-site reactions such as: redness, pain/tenderness, firmness, swelling, lumps/bumps, bruising, itching, and discoloration. As with all skin-injection procedures, there is a risk of infection.

### **Are there any reasons why I should not receive JUVÉDERM™ or VOLUMA™?**

Your clinician will ask about your medical history to determine if you are an appropriate candidate for treatment. JUVÉDERM™ and VOLUMA™ should not be used in patients who have: Severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies or patients with a history of allergies to Gram-positive bacterial proteins. Do not use JUVÉDERM™ or VOLUMA™ if you are allergic to lidocaine.

### **What should my clinician advise me about?**

The following are important treatment considerations for you to discuss with your clinician and understand in order to help avoid unsatisfactory results and complications. Patients who are using substances that can prolong bleeding, such as aspirin, ibuprofen and other NSAIDS, vitamin E and fish oil, 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. Ideally you should not take these medications for 5 days prior to treatment.

If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with JUVÉDERM™ or VOLUMA™, there is a possible risk of an inflammatory reaction at the treatment site. JUVÉDERM™ and VOLUMA™ 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. The safety of JUVÉDERM™ and VOLUMA™ for use during pregnancy, in breastfeeding females, or in patients under 18 years has not been established. The safety

of JUVÉDERM™ and VOLUMA™ in patients with a history of excessive scarring (eg, hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied.

**What should my clinician warn me about?**

The safety and effectiveness of JUVÉDERM™ for the treatment of areas other than facial wrinkles and folds (such as lips) have not been established in controlled clinical studies.

**Do the injections hurt?**

Injections may cause some discomfort during and after the injection. JUVÉDERM™ and VOLUMA™ are injected directly into the skin using a fine needle to reduce injection discomfort. There is Xylocaine in the product to make treatments more comfortable

**What should I expect following the procedure?**

Your clinician will tell you what to expect following treatment with JUVÉDERM™ and VOLUMA™. 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. Depending on your needs, multiple syringes may be necessary to achieve full correction.

**What other treatments are available to me?**

Other treatments for dermal soft-tissue augmentation include bovine-based collagen and other hyaluronic acid-based dermal fillers. Aside from these treatments, additional options for the correction of lines and wrinkles do exist, including facial creams, BOTOX® Cosmetic (Botulinum Toxin Type A), chemical peels, and laser skin surface treatments, and may be discussed with your clinician.

**When should I notify my clinician?**

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

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

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**Consent**

I have read the information about JUVÉDERM™ and VOLUMA™ in its entirety and have discussed the risks and benefits of dermal filler treatment with my clinician. I understand the information provided. I agree to my being treated with JUVÉDERM™ and/or VOLUMA™.

Patient's Signature

Date

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I have discussed the risks and benefits of dermal filler treatment with this patient, have answered his/her questions, and find him/her an appropriate candidate for treatment with JUVÉDERM™ and/or VOLUMA™.

Clinician Signature \_\_\_\_\_

Date \_\_\_\_\_