

# JUVÉDERM VOLLURE™ XC

## DRAFT Patient Information Labeling

### About JUVÉDERM VOLLURE™ XC

Before beginning your treatments, please review this important information.

## 1. GLOSSARY

(Note that terms in the glossary are bold throughout this document.)

**Anesthetic**—a substance that reduces sensitivity to pain

**Asymmetry Correction**—an additional treatment with dermal filler that is given to balance the effect after the initial treatment has worn off on one side of the face

**Hyaluronic acid (HA)**—a polysaccharide (sugar) that is naturally in the body. It keeps skin moisturized and soft. HA fillers, including the JUVÉDERM® range of products, are a modified form of the HA that is naturally in your body

**Lidocaine**—a synthetic compound used as a local anesthetic to decrease pain

**Nasolabial folds (NLFs)**—the lines or wrinkles that run from the corners of the nose downward toward the corners of the mouth

**Pigmentation disorders**—a medical condition that results in a change in skin color

**Repeat injection**—an additional treatment with dermal filler that is given after the effects of the initial treatment have worn off, in order to maintain the desired result

**Touch-up**—an additional injection of a small amount of dermal filler usually given about 2 weeks to 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result

**VYCROSS® technology**—a unique manufacturing process that provides a high concentration of crosslinked HA for long-lasting results. It creates a smooth-consistency gel that flows easily into the skin.

## 2. PRODUCT DESCRIPTION

### What is it?

JUVÉDERM VOLLURE™ XC injectable gel is a smooth, clear, colorless **hyaluronic acid (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 help retain natural moisture and softness. The **lidocaine** helps to improve the comfort of the injection.

JUVÉDERM VOLLURE™ XC injectable gel is manufactured using **VYCROSS® technology** to give a specialized smooth-gel filler that produces long-lasting results for up to 18 months at the treatment site.

### What is it for?

JUVÉDERM VOLLURE™ XC is injected with an ultrafine needle into areas of facial tissue where moderate to severe facial wrinkles and folds (such as **nasolabial folds**) occur.

### How does it work?

As you age, wrinkles develop on your face, and **nasolabial folds** may become more visible.

JUVÉDERM VOLLURE™ XC is designed to temporarily reverse signs of aging by adding subtle volume to facial wrinkles and folds (such as nasolabial folds) and restoring a smoother appearance to the face in patients over the age of 21. The **lidocaine** in the gel improves the comfort of the injection by reducing sensitivity to pain.

### 3. CONTRAINDICATIONS

#### **Are there any reasons why I should not receive JUVÉDERM VOLLURE™ XC injectable gel?**

Your doctor will ask about your medical history to determine if JUVÉDERM VOLLURE™ XC is right for you. You should not use JUVÉDERM VOLLURE™ XC if:

- You have severe allergies with a history of severe reactions (anaphylaxis) or history of presence of multiple severe allergies. Use may result in an allergic reaction.
- You are allergic to **lidocaine** or to the proteins used to make the **HA** in JUVÉDERM VOLLURE™ XC (Gram-positive bacterial proteins). Use may result in an allergic reaction.

If you are not sure about your medical history concerning these allergies, please discuss further with your doctor.

### 4. PRECAUTIONS

#### **What precautions should my doctor advise me about?**

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

- Avoid strenuous exercise, exposure to extensive sun or heat, and consumption of alcoholic beverages within the first 24 hours following treatment. These may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are using any medication that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may increase bruising or bleeding at the injection site.
- Tell your doctor if you are planning laser treatment, chemical peeling, or any other procedure after treatment with JUVÉDERM VOLLURE™ XC. There is a possible risk of an inflammatory reaction at the treatment site.
- Tell your doctor which areas of your face you would like to have treated. This product is intended for use in moderate to severe facial wrinkles and folds such as nasolabial folds. The safety and effectiveness for treatment in other areas have not been established in controlled, clinical studies.
- Tell your doctor if you are on therapy used to decrease the body's immune response. Use may result in an increased risk of infection.
- Tell your doctor if you are pregnant or breastfeeding. The safety for use during pregnancy, or in women who are breastfeeding, has not been studied.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of JUVÉDERM VOLLURE™ XC injectable gel in patients with a history of excessive scarring has not been studied and may result in additional scars.
- Tell your doctor if you have a history of **pigmentation disorders**. The safety of JUVÉDERM VOLLURE™ XC in patients with a history of **pigmentation**

**disorders** has not been studied. Use in these patients may result in changes in pigmentation.

## 5. CLINICAL STUDY

### **How was the product studied?**

To establish the safety and effectiveness of JUVÉDERM VOLLURE™ XC for smoothing the appearance of facial wrinkles and folds, 123 subjects were treated with JUVÉDERM VOLLURE™ XC in 1 **NLF** and another dermal filler (control) in the opposite **NLF**. To achieve subjects' desired results, an optional **touch-up** treatment was allowed 1 month after initial treatment, and 24 subjects elected to receive **asymmetry correction** at 9, 12, or 15 months. Between 12 to 18 months 84 subjects elected to receive a repeat treatment.

The amount of JUVÉDERM VOLLURE™ XC used in the clinical study to achieve optimal outcomes ranged from 0.1 mL to 3.0 mL per **NLF**, with a median volume of 1.7 mL. To maintain the desired results, approximately one-third of the amount (0.6 mL) per **NLF** was needed for the **repeat injection**.

To evaluate the safety of JUVÉDERM VOLLURE™ XC, subjects noted common side effects in daily diaries. Side effects were also reported by doctors during office visits with each subject. These office visits included discussing any symptoms or complaints with the subjects and assessing the appearance of the subjects' **NLFs**. To evaluate the effectiveness of the product, a 5-point Wrinkle Assessment Scale was used.

## 6. BENEFITS

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

The results of the JUVÉDERM VOLLURE™ XC clinical study showed that the product will temporarily smooth and reduce the appearance of moderate to severe facial wrinkles and folds such as nasolabial folds.

### **What did the clinical study show?**

JUVÉDERM VOLLURE™ XC was found to effectively smooth and reduce the appearance of moderate to severe facial wrinkles and folds. The clinical study showed that JUVÉDERM VOLLURE™ XC lasted through 18 months in the majority (59%) of subjects.

The study doctors reported that:

- 93% of subjects had a 1-point-or-greater improvement in **NLF** severity 6 months after treatment
- 59% of subjects had a 1-point-or-greater improvement in **NLF** severity 18 months after treatment

The subjects reported:

- Approximately 82% of the subjects were highly satisfied with their treatment results 6 months after the injection
- Approximately 68% of the subjects were highly satisfied with their treatment results 18 months after the injection
- Improvement in the appearance of their **NLFs** based on how bothered they were with the depth of their **NLF**, the look of their **NLF** when relaxed and

smiling, how old their NLF makes them look, and how their NLF looks compared with other people their age

- 96% of subjects improved in the appearance of their NLFs at 6 months
- 62% of subjects improved in the appearance of their NLFs at 18 months

## 7. RISKS

### What side effects were seen in the clinical study?

Subjects reported side effects in 30-day daily diaries. If these side effects lasted longer than 30 days, they were reported as adverse events. Adverse events could also be reported by doctors at any time throughout the study.

Based on the clinical study, the likelihood of experiencing side effects after treatment with JUVÉDERM VOLLURE™ XC is shown below in Table 1. A majority of subjects (95%) in the clinical study experienced a side effect, such as firmness, swelling, tenderness to touch, lumps/bumps, redness, pain, bruising, itching, and discoloration at the injection site, as reported in their 30-day daily diaries. These side effects were usually mild (easily tolerated) or moderate (uncomfortable) in severity, although some subjects experienced severe side effects (incapacitating). The majority of the side effects went away on their own within 1 week. Some side effects lasted longer than 1 week. The most common side effects that lasted longer than 1 week were firmness (43%) and lumps/bumps (36%).

**Table 1: Side Effects After Treatment<sup>a,b</sup>**

| Side Effect         | Likelihood of Experiencing Side Effect |
|---------------------|--|
| Any Side Effect     | 95 out of 100 people (95%)             |
| Firmness            | 89 out of 100 people (89%)             |
| Swelling            | 86 out of 100 people (86%)             |
| Tenderness to Touch | 84 out of 100 people (84%)             |
| Lump/Bumps          | 82 out of 100 people (82%)             |
| Redness             | 74 out of 100 people (74%)             |
| Pain                | 72 out of 100 people (72%)             |
| Bruising            | 57 out of 100 people (57%)             |
| Itching             | 31 out of 100 people (31%)             |
| Discoloration       | 27 out of 100 people (27%)             |

<sup>a</sup> Occurring in > 5% of subjects.

<sup>b</sup> Based on 122 subjects who provided information about side effects after their initial treatment.

### What adverse events were seen in the clinical study?

Adverse events (any side effects that lasted longer than the 30-day daily diary, or adverse events reported by doctors at any time throughout the study) were reported over the course of the study. After treatment with JUVÉDERM VOLLURE™ XC, most of the adverse events were rated as mild or moderate. The most common adverse events for subjects were the same as those reported in the daily diary, such as firmness, lumps/bumps, and swelling. Severe adverse events included firmness, lumps/bumps, swelling, itching, redness, and bruising. Most of these adverse events went away on their own within without any long-term effects. One subject had mild swelling that did not go away by the end of the study.

Subjects experienced similar adverse events after **repeat injection**.

In the clinical study, 3 adverse events occurred weeks to months after the injection procedure. These events included mild swelling, moderate skin mass, and severe itching. The swelling was treated with anti-inflammatory medicines, the skin mass was treated with a topical corticosteroid cream, and the itching did not require any treatment. All 3 events went away without any long-term effects.

### **What are other possible adverse events?**

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

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.

Although most side effects will go away with time, your doctor may choose to treat them with medications, such as antibiotics, steroids, or hyaluronidase (an enzyme that breaks down **HA**).

## **8. BEFORE PROCEDURE INFORMATION**

### **What happens in the office before the injection?**

Note that each doctor may have a unique process for assessing and treating patients. The following is an example of what you would likely experience with a typical procedure.

Before the injection procedure, your doctor will ask you questions about your medical history, as well as your treatment goals. Your doctor will discuss whether you are an appropriate candidate for JUVÉDERM VOLLURE™ XC and review what to expect during and after treatment, including possible side effects. Your doctor will also examine your skin in and around the treatment area, and may take photos. Different options for pain management will be discussed, and if pretreatment numbing is desired, a numbing agent such as **lidocaine** cream, or other **anesthetic** agent may be used. The treatment area will be cleaned and then prepared with alcohol or other antiseptic. Your doctor may use a pen to mark your face, identifying the planned areas of injection.

## **9. PROCEDURE DESCRIPTION**

### **What happens during the procedure?**

After the first injection, your doctor will wait a few seconds to allow the **lidocaine** to take effect before moving forward with the rest of the treatment. JUVÉDERM VOLLURE™ XC will be injected in small amounts into the treatment area until the desired aesthetic outcome is achieved. Your doctor may massage the treatment area gently to assure that the product integrates in the skin and is evenly distributed for a smooth appearance. Ice may be applied for a brief period following treatment to minimize swelling and reduce pain.

### **Do the injections hurt?**

Injections may cause some discomfort during and after the procedure. In the JUVÉDERM VOLLURE™ XC clinical study, immediately after the injection, subjects rated pain, on average, as a 2.3 on an 11-point scale where 0 is no pain and 10 is the worst pain imaginable. JUVÉDERM VOLLURE™ XC contains **lidocaine** to reduce pain at the injection site. Your

doctor may also choose to numb (anesthetize) the treatment area with a numbing agent to further minimize discomfort.

## **10. AFTER PROCEDURE INFORMATION**

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

In the JUVÉDERM VOLLURE™ XC clinical trial, the most common side effects were temporary reactions at the injection site such as firmness, swelling, tenderness to touch, lumps/bumps, redness, pain, bruising, itching, and discoloration. These side effects usually lasted 1 week or less. See Section 7 for additional information on side effects seen in the clinical study.

Your doctor will tell you what to expect following treatment with JUVÉDERM VOLLURE™ XC. Within the first 24 hours, you should avoid strenuous exercise, exposure to extensive sun or heat, and consumption of 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 doctor when makeup may be applied after your treatment.

### **Will I need more than one treatment to achieve my desired result?**

You should discuss your treatment goals and plan with your doctor. In the JUVÉDERM VOLLURE™ XC clinical study, 51% of subjects received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired result.

### **Do the results last forever?**

No. While individual results may vary, in the clinical study, the results lasted for 18 months in a majority (59%) of subjects treated with JUVÉDERM VOLLURE™ XC. After this, **repeat injections** are usually needed to maintain your desired result.

## **11. WHEN TO CALL YOUR DOCTOR**

### **When should I call my doctor?**

Call your doctor immediately if you have:

- 1) Changes in your vision
- 2) 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)
- 3) White appearance of the skin
- 4) Unusual pain during or shortly after treatment

Be sure to call your doctor if you have:

- 1) Significant pain away from the injection site
- 2) Any redness and/or visible swelling that lasts for more than a few days
- 3) Any side effect that occurs weeks or months after treatment
- 4) Any other symptoms that cause you concern

## **12. ADDITIONAL INFORMATION**

If you believe that you have experienced a serious problem related to JUVÉDERM VOLLURE™ XC injectable gel, you should call your doctor. You may also contact the Allergan Product Surveillance line during normal business hours at 1-877-345-5372 to report

any side effects.

**What should I do if I have additional questions?**

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

[Allergan logo]

© 2017 Allergan. All rights reserved.

All trademarks are the property of their respective owners.

Patented. See: [www.allergan.com/products/patent\\_notices](http://www.allergan.com/products/patent_notices).

**www.juvederm.com** 03/2017 163852