

Before beginning your treatments, please review this important information.

## 1. GLOSSARY

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

**Abscess**—a swollen lump filled with pus

**Aesthetic**—cosmetic, related to beauty

**Anaphylaxis**—severe allergic reaction

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

**Angioedema**—sudden swelling below the skin surface

**Anticoagulants**—a substance that prevents or reduces blood clots

**Arnica**—an herbal ointment that is commonly used to treat pain, bruising, and swelling

**Epinephrine**—a medication used in emergencies to treat serious allergic reactions

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

**Hyaluronidase**—an enzyme that breaks down hyaluronic acid

**Inflammatory reaction**—a localized response to injury, typically including pain, heat, redness, and swelling

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

**Necrosis**—death of living tissue (skin)

**Optimal**—the best possible outcome

**Pigmentation disorders**—a lightening or darkening of an area of the skin

**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

**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 usually given about 2 weeks to 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result

**Vasodilators**—medicines that open blood vessels

## 2. PRODUCT DESCRIPTION

### What is it?

JUVÉDERM® Ultra XC injectable gel is a 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 deliver nutrients and help the skin retain its natural moisture and softness. The **lidocaine** helps to improve the comfort of the injection.

### How does it work?

JUVÉDERM® Ultra XC is a crystal-clear gel that is injected directly into and around the lips using a small needle to temporarily add the desired range of fullness for lip enhancement in adults 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® Ultra XC injectable gel?

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

- You have severe allergies, marked by a history of severe reactions (**anaphylaxis**) or history or 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® Ultra 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 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.

- Minimize strenuous exercise and exposure to extensive sun or heat within the first 24 hours following treatment. Exposure to any of 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® Ultra XC. There is a possible risk of an **inflammatory reaction** at the treatment site.
- 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, in breastfeeding females, or in patients under 18 years has not been studied.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of JUVÉDERM® Ultra 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® Ultra XC in patients with a history **pigmentation disorders** has not been studied. Use in these patients may result in changes in pigmentation.

## 5. CLINICAL STUDY

### How was the product studied?

The safety and effectiveness of JUVÉDERM® Ultra XC for improving lip fullness was studied in 208 subjects. To achieve subjects' desired lip fullness results, a **touch-up** treatment was allowed 2 weeks to 1 month after their initial treatment. After 1 year, or after correction had been lost, whichever was first, subjects were offered a **repeat injection**.

The amount of JUVÉDERM® Ultra XC used in the clinical study to achieve **optimal** outcomes ranged from 0.3 mL to 4.8 mL, with a median volume of 2.2 mL. In general, the amount of JUVÉDERM® Ultra XC used for the **touch-up** and **repeat injection** was less than the first treatment. For each subject, the volume used was based on the starting lip fullness and treatment goals.

To evaluate the safety of JUVÉDERM® Ultra XC, subjects noted common side effects in their daily diaries. Side effects were also reported by doctors based on office visits with each subject. These office visits included discussing any symptoms or complaints with the subjects, and assessing their appearance. To evaluate the effectiveness of the product for lip enhancement, a 5-point scale (ranging from 1 to 5) was used.

## 6. BENEFITS

### What will it accomplish?

The results of the JUVÉDERM® Ultra XC clinical study showed that the product will temporarily improve lip fullness.

### What did the clinical study show?

JUVÉDERM® Ultra XC was found to effectively increase lip fullness.

- 79% of subjects had at least a 1-point improvement in lip fullness 3 months after treatment
- 56% of subjects had at least a 1-point improvement in lip fullness 1 year after treatment
- 82% of subjects at 3 months reported that their treatment goals were met
- More than 75% of subjects reported an improvement in their overall satisfaction with the look and feel of their lips at 1 year after their last treatment
- The majority of subjects reported improvement in the softness, smoothness, and natural look and feel of their lips and mouth through 1 year

The clinical study showed that JUVÉDERM® Ultra XC lasts up to 1 year in the majority of subjects.

## 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.

Subjects in the clinical study experienced swelling, bruising, firmness, lumps/bumps, tenderness, redness, pain, discoloration, itching, and peeling at the injection site, as reported in their 30-day daily diaries. These side effects were usually mild (causing little discomfort and no effect on daily activities) or moderate (causing some discomfort and some effect on daily activities) in severity, although some subjects experienced severe side effects (causing great discomfort and effect on daily activities). Most of these side effects lasted 14 days or less and went away on their own. Occasionally, some subjects experienced side effects that lasted longer than 14 days. Based on the clinical study, the likelihood of experiencing side effects after treatment with JUVÉDERM® Ultra XC is shown in Table 1.

## What side effects were seen in the clinical study? (continued)

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

Side Effects	Likelihood of Experiencing Side Effects
Any Side Effect	99 out of 100 people (99%)
Swelling	96 out of 100 people (96%)
Bruising	93 out of 100 people (93%)
Firmness	90 out of 100 people (90%)
Lumps/Bumps	88 out of 100 people (88%)
Tenderness	85 out of 100 people (85%)
Redness	78 out of 100 people (78%)
Pain	74 out of 100 people (74%)
Discoloration	36 out of 100 people (36%)
Itching	29 out of 100 people (29%)
Peeling	7 out of 100 people (7%)

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

<sup>b</sup>Based on 193 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 to JUVÉDERM® Ultra XC 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. The most common adverse events were the same as those reported as side effects in the daily diary, such as lumps/bumps, firmness, and discoloration.

In the clinical study, 4 subjects had 11 severe (great discomfort affecting daily activities) adverse events. These events included **angioedema**, swelling, bruising, lumps/bumps, redness, pain, and wrinkling. All of these events resolved within 1 month without any long-term effects. Medical treatment was needed in some cases.

### What side effects have been reported through voluntary postmarket surveillance of JUVÉDERM® Ultra and JUVÉDERM® Ultra Plus (with or without lidocaine) use in and outside of the United States?

The most commonly reported adverse events were swelling, redness, bruising, and pain.

- Swelling, redness, and pain generally occurred from immediately to 2 months after injection. The treatment prescribed included **NSAIDs**, antihistamines, antibiotics, steroids, **arnica**, and **hyaluronidase**. In most cases, these went away within a few days to 5 weeks.
- Bruising generally occurred from immediately to 1 day after injection. Treatment included **NSAIDs**, antihistamines, antibiotics, steroids, **arnica**, and **hyaluronidase**. In most cases, it went away within a few days to 6 weeks.

Additionally, there have been reports of nodules, infection, inflammation, allergic reaction, and blood vessel blockage.

- Nodules generally occurred from immediately to 2 months after injection. Treatment included **NSAIDs**, antibiotics, steroids, and **hyaluronidase**. In most cases, nodules went away within 1 month.
- Infection generally occurred from immediately to 1 month after injection. Treatment included antibiotics, pain killers, antifungals, and antibacterial medicines.
- Inflammation generally occurred from the day of treatment to 4 months after injection. Treatment included antibiotics, steroids, and needle aspiration. Resolution of symptoms has been reported within 4 days.
- Allergic reaction generally occurred from immediately to 1 day after injection. Treatment included steroids and antihistamines.
- Blood vessel blockage generally occurred from immediately to 1 week after injection. Treatment included **anticoagulants**, **epinephrine**, **NSAIDs**, **vasodilators**, **hyaluronidase**, surgery, and warm compress. Outcomes have ranged from completely resolved to ongoing at time of last contact.

Other adverse events that were reported included: blister, skin rash, bleeding at the injection site, **necrosis** at the injection site, **abscess** at the injection site, increase or decrease in sensation, skin discoloration, device migration, dry skin, headache, flu-like symptoms, vision abnormalities, herpes, anxiety, scarring, dizziness, nausea, depression, lack or loss of correction, unsatisfactory result, overcorrection, varied injuries, discomfort, drainage, product coming back out, acne, shortness of breath, passing out, cardiac complication, deeper wrinkle, collection of blood outside of a blood vessel, swelling from reactive blood vessels, spider vein, cyst, and tissue hardening.

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.

### 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 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 or adverse events will resolve within 2 weeks, some side effects or adverse events may persist longer than 30 days. Your doctor may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase** (an enzyme that breaks down and dissolves **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 JUVÉDERM® Ultra XC is right for you and review what to expect during and after treatment, including possible side effects. Your doctor will also examine your skin and/or lips 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 **topical** 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® Ultra 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 is evenly distributed. 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. JUVÉDERM® Ultra XC contains **lidocaine** to reduce injection-site pain. Your doctor may also choose to numb (anesthetize) the treatment area with a **topical** or injected numbing agent to further minimize discomfort.

## 10. AFTER PROCEDURE INFORMATION

### What should I expect following the procedure?

In the JUVÉDERM® Ultra XC clinical trial, the most common side effects were temporary reactions at the treatment site such as tenderness, swelling, firmness, lumps/bumps, and bruising. These side effects usually lasted 14 days or less. See Section 7 for additional information on side effects seen in the clinical study.

Your doctor will also tell you what to expect following treatment with JUVÉDERM® Ultra XC. Within the first 24 hours, you should minimize strenuous exercise and exposure to extensive sun or heat. Exposure to any of the above may increase temporary redness, swelling, and/or itching at the injection site. 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® Ultra XC clinical study, 44% of subjects received a **touch-up** treatment 2 weeks to 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 1 year in a majority of subjects treated with JUVÉDERM® Ultra 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 also 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® Ultra 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.

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