

Introduction

Before beginning your treatments, please review this important information.

Glossary of terms

Aesthetic—cosmetic, related to beauty

Anaphylaxis—severe allergic reaction

Bovine-based collagen—a dermal filler created from cow hides

Complimentary—free, at no cost

Cushioning agent—absorbs shock

Duration—length of time

Expressed a preference—subjects liked better

Gram-positive bacterial proteins—remnants of protein from the bacteria that produce the hyaluronic acid used in JUVÉDERM® Ultra XC

Hyaluronidase—an enzyme that breaks down hyaluronic acid

Hypertrophic scarring—a thick, hard scar that grows over the injured area

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

Injection-site responses—side effects from treatment

Keloid formation—a thick, hard scar that grows outside the injured area

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

NSAID—Nonsteroidal anti-inflammatory drug, such as aspirin or ibuprofen

Optimal—the best possible outcome

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

Topical—cream or ointment applied to a certain area of the skin and affecting only the area to which it is applied

What is it?

JUVÉDERM® Ultra XC injectable gel is a colorless hyaluronic acid gel that contains a small quantity of local anesthetic (lidocaine) and is injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth. 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. The role of lidocaine is to reduce the pain associated with injections into the skin.

What does it do?

JUVÉDERM® Ultra 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?

JUVÉDERM® Ultra XC is injected into areas of facial tissue where moderate to severe facial wrinkles and folds occur. It temporarily adds volume to the skin and may give the appearance of a smoother surface.

What will it accomplish?

JUVÉDERM® Ultra XC injectable gel will help to smooth moderate to severe facial wrinkles and folds. Most patients need 1 treatment to achieve optimal wrinkle smoothing, and the results last about 9 months to 1 year.

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.

Rarely, vision abnormalities have been reported after treatment with JUVÉDERM® Ultra XC.

Are there any reasons why I should not receive JUVÉDERM® Ultra 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 facial wrinkles and folds (such as lips) 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.

- 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 injection site. You should inform your physician before treatment if you are using these types of substances
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with JUVÉDERM® Ultra XC, there is a possible risk of an inflammatory reaction at the treatment site
- JUVÉDERM® Ultra XC injectable gel 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 for use during pregnancy, in breast-feeding females, or in patients under 18 years has not been established
- The safety in patients with a history of excessive scarring (eg, hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied

What did the clinical study show?

In the primary US clinical study to establish safety and effectiveness, 146 subjects were followed for 24 weeks after injection with JUVÉDERM® Ultra (without lidocaine) in 1 nasolabial fold (NLF) and ZYPLAST® dermal filler (bovine-based collagen) in the other. The percentage of subjects who reported common injection-site responses are presented in the table below.

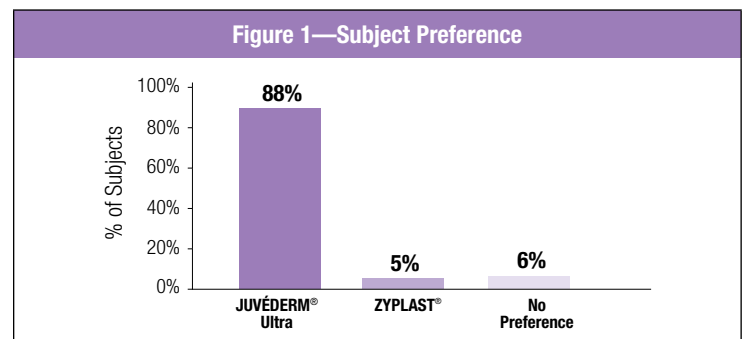
Injection-Site Responses	JUVÉDERM® Ultra		ZYPLAST®	
	n ^b	%	n ^b	%
Redness	136	93%	130	89%
Pain/tenderness	131	90%	128	88%
Firmness	129	88%	127	87%
Swelling	125	86%	122	84%
Lumps/bumps	115	79%	122	84%
Bruising	86	59%	80	55%
Itching	52	36%	53	36%
Discoloration	48	33%	49	34%

^a Occurring in > 5% of subjects.

^b Number of subject NLFs with each specific injection-site response.

Injection-site responses were similar in duration and frequency for the JUVÉDERM® Ultra injectable gel and ZYPLAST® treated sides, were usually mild or moderate in severity, did not require intervention, and lasted 7 days or less.

JUVÉDERM® Ultra was found to provide a more persistent wrinkle correction than ZYPLAST® dermal filler over the 24-week course of the study. The percentage of subjects who maintained improvement with JUVÉDERM® Ultra at 24 weeks was 88% compared to 36% with ZYPLAST®. At the conclusion of the study, 129 (88%) of the 146 subjects expressed a preference for JUVÉDERM® Ultra injectable gel, while only 8 (5%) expressed a preference for ZYPLAST®, and 9 (6%) had no preference.



Subjects who completed the 24-week study were invited to return for a complimentary repeat treatment. Subjects returned at their (or their physician's) convenience. Of the 146 subjects, 116 (79%) returned for repeat treatment, on average at 9 months after their last injection. Forty-eight (48) subjects returned more than 36 weeks (9 months) after their last injection: the percentage of those subjects who had maintained improvement with JUVÉDERM® Ultra was 75%.

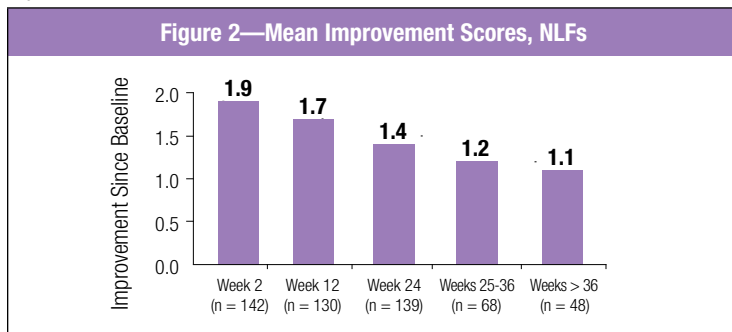
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What did the clinical study show? (continued)

At multiple time points in the clinical study, subjects' nasolabial folds were rated on a scale from 0 to 4:

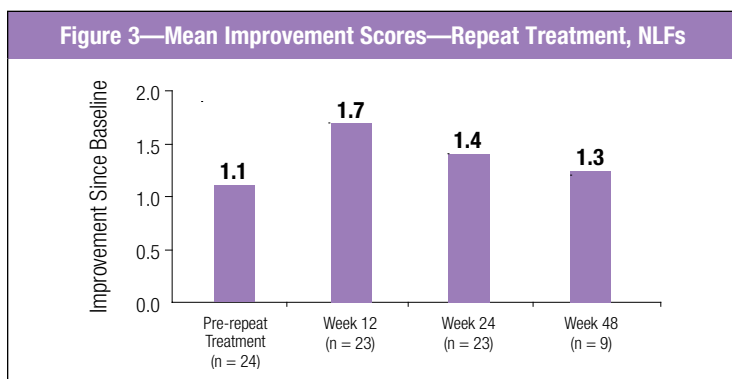
Using this 5-point wrinkle assessment scale, the mean improvement since baseline was 1.9 at 2 weeks, 1.4 at 24 weeks, and 1.1 beyond 36 weeks after treatment.

0	None
1	Mild
2	Moderate
3	Severe
4	Extreme

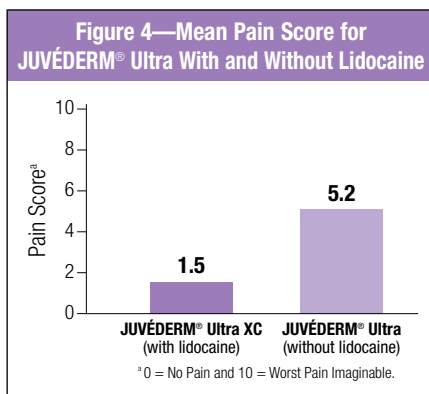


A subset of these subjects enrolled in a second study that followed subjects for 24-48 weeks after repeat treatment. Twenty-four (24) subjects were enrolled in the study. Twenty-three (23) were evaluated at 24 weeks (6 months) after repeat treatment with 87% maintaining improvement. Nine (9) subjects returned for evaluation 48 weeks (1 year) after repeat treatment: the percentage of those subjects who had maintained improvement with JUVÉDERM® Ultra injectable gel was 78%.

The mean improvement since baseline (ie, the average improvement from before treatment in patients using the wrinkle assessment scale listed in Table 2) was 1.4 at 24 weeks and 1.3 at 48 weeks after repeat treatment.



In another clinical study comparing JUVÉDERM® Ultra with and without lidocaine, 36 subjects received the product with lidocaine in 1 nasolabial fold and the product without lidocaine in the other. Subjects rated the level of pain during each injection. Pain was significantly less on the side that received JUVÉDERM® Ultra XC, and in comparing the 2 injections, 34 subjects (94%) found the lidocaine formulation to be less painful.



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

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

- Swelling and bruising generally occurred from immediately to 2 weeks postinjection. Treatment included arnica, NSAIDs, antihistamines, antibiotics, steroids, and hyaluronidase. In most cases, they went away within a day to one month
- Redness generally occurred from immediately to one week postinjection. Treatment included arnica, antihistamines, antibiotics, steroids, hyaluronidase, and laser treatment. In most cases, it went away within 1 to 4 weeks

- Itching generally occurred from immediately to one week postinjection. Treatment included NSAIDs, antihistamines, antibiotics, and steroids. In most cases, it went away within 3 days to 2 months
- Firmness generally occurred from one day to 2 months postinjection. Treatment included antihistamines, antibiotics, steroids, and hyaluronidase. In most cases, it went away within one week
- Pain generally occurred from immediately to 8 days postinjection. Treatment included NSAIDs, antihistamines, antibiotics, steroids, and hyaluronidase. In most cases, it went away within 1 to 6 weeks

Additionally there have been reports of nodules, infection, allergic reaction, inflammation, abscess, deeper wrinkle/scar, and displacement.

- Nodules generally occurred from immediately to 2 weeks postinjection. Treatment included arnica, NSAIDs, antibiotics, steroids, hyaluronidase, and removal with a needle. In most cases, they went away within 3 days to 1 month
- Infection generally occurred from immediately to 1 week postinjection. Treatment included NSAIDs, antibiotics, and steroids. In most cases, it went away within 6 to 10 days
- Allergic reaction generally occurred from immediately to 2 months postinjection. Treatment included antihistamines, antibiotics, steroids, and hyaluronidase. In most cases, they went away within 2 days to 4 months
- Inflammation generally occurred from immediately to 2 weeks postinjection. Treatment included antihistamines, antibiotics, steroids, and hyaluronidase. In most cases, it went away within 3 days to 2 months
- Abscess generally occurred from 2 days to 2 weeks postinjection. Treatment included antibiotics, steroids, and hyaluronidase. In most cases, it went away within 4 to 6 weeks
- Deeper wrinkle/scar generally occurred from immediately to 2 weeks postinjection. Treatment included antibiotics, steroids, and surgical correction of the scar. Deeper wrinkle/scar has been reported infrequently but more commonly after treatment in the glabellar region (the area between the eyebrows)
- Displacement (movement of product) generally occurred from immediately to 2 weeks postinjection. Treatment included antibiotics, steroids, hyaluronidase, and laser treatment

Other events that were reported included: blister, tingling sensation (paresthesia), bleeding at the injection site, skin rash, feeling of discomfort (malaise), headache, skin whitening (blanching), vision abnormalities, hives (urticaria), herpes simplex, dilated small blood vessels (telangiectasis), rapid swelling (angioedema), flu-like symptoms, nausea, vascular event, shortness of breath (dyspnea), rash (dermatitis), and granuloma at the injection site.

Do the injections hurt?

Some discomfort may occur during and after the injection. JUVÉDERM® Ultra XC injectable gel 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® Ultra 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. Less material (about half the amount) is usually needed for repeat injections.

What other treatments are available to me?

There are a variety of dermal fillers available in the United States that may be used for treatment. Aside from these, additional options for the correction of lines and wrinkles do exist, including facial creams, BOTOX® Cosmetic (onabotulinumtoxinA), chemical peels, and laser skin surface treatments. 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 at 1-877-345-5372.



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Before beginning your treatments, please review this important information.

1. GLOSSARY

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

Aesthetic—cosmetic, related to beauty

Anaphylaxis—severe allergic reaction

Anesthetic—a substance that reduces sensitivity to pain

Angioedema—sudden swelling below the skin surface

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

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

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 below in Table 1.

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%)

^aOccurring in > 5% of subjects

^bBased 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 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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