About JUVÉDERM® VOLUMA™ XC for Cheek Augmentation

JUVÉDERM®
VOLUMA™ XC

Before beginning your treatments, please review this important information.

1. GLOSSARY

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

Abscess—a swollen lump filled with pus

Anesthetic—a substance that reduces sensitivity to pain

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

BDDE—a small biodegradable compound added to crosslink the HA in the gel

Cannula—a thin metal tube with a blunt tip

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 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

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

Necrosis—death of living tissue (skin)

NSAIDs—nonsteroidal anti-inflammatory medicine, such as aspirin or ibuprofen

Pigmentation disorder—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

Topical—a cream or ointment applied on top 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

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 and provides a smooth, natural look and feel

2. PRODUCT DESCRIPTION

What is it?

JUVÉDERM® VOLUMA™ XC injectable gel is a smooth, 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 addition of **lidocaine** helps to improve the comfort of the injection. JUVÉDERM® VOLUMA™ XC injectable gel is manufactured using **VYCROSS® technology**; during which, a small amount of the biodegradable compound **BDDE** is added to crosslink the HA in the gel. **VYCROSS® technology** results in a specialized smooth-gel filler that produces long-lasting results at the treatment site. JUVÉDERM® VOLUMA™ XC is delivered by an injection into the cheek and surrounding area of the mid-face to correct volume and fullness.

3. INDICATION/INTENDED USE

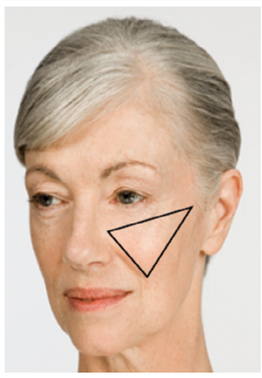
What is it for?

JUVÉDERM® VOLUMA™ XC is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.

What does it do?

As you age, the cheek area loses its youthful shape. The cheeks flatten out and the skin may begin to sag. JUVÉDERM® VOLUMA™ XC injectable gel is designed to temporarily reverse these signs of aging. It is a gel that is injected into the cheek area to lift the skin. It temporarily adds volume to the cheek area and results in a smoother contour and more youthful appearance to the face. Figure 1 shows the treatment area for JUVÉDERM® VOLUMA™ XC.

Figure 1. Treatment Area for JUVÉDERM® VOLUMA™ XC for Cheek Augmentation



How is it used?

It is injected into the cheek area using a small needle or **cannula**. It temporarily corrects volume in the cheek area and gives the appearance of a more youthful, smoother skin surface.

4. CONTRAINDICATIONS

Are there any reasons why I should not receive JUVÉDERM® VOLUMA™ XC injectable gel?

Your doctor will ask about your medical history to determine if you are an appropriate candidate for treatment.

- You should not use the product if you have severe allergies with a history of severe reactions (anaphylaxis). Use may result in an allergic reaction
- You should not use the product if you are allergic to **lidocaine** or to the proteins used to make the **HA** in JUVÉDERM® VOLUMA™ XC (Gram-positive bacterial proteins). Use may result in an allergic reaction

5. 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 pregnant or breastfeeding. The safety of JUVÉDERM® VOLUMA™ XC injectable gel for use during pregnancy, or in women who are breastfeeding, has not been studied.
- Tell your doctor your age and discuss how your age may influence your decision to use this product. The safety of JUVÉDERM® VOLUMA™ XC has not been studied in patients under 35 years or over 65 years.
- Tell your doctor which areas of your face you would like to have treated. This product is intended for use in the cheek and chin (refer to the JUVÉDERM® VOLUMA™ XC Patient Label for Chin Augmentation) areas. The safety and effectiveness for treatment in other areas have not been established in controlled, clinical studies.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of JUVÉDERM® VOLUMA™ 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® VOLUMA™ XC in patients with a history of **pigmentation disorders** has not been studied. Use in these patients may result in changes in pigmentation.
- Tell your doctor if you are on therapy used to decrease the body's immune response (immunosuppressive therapy). Use may result in an increased risk of infection.
- Tell your doctor before treatment if you are using substances that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may result in increased bruising or bleeding at the injection site.
- Patients who experience skin injury near the site of JUVÉDERM® VOLUMA™ XC implantation may be at a higher risk for adverse events.
- The safety of JUVÉDERM® VOLUMA™ XC with **cannula** has not been established in patients with darker skin types (Fitzpatrick Skin Types V and VI).

6. RISKS

What are possible side effects?

In the clinical study, most side effects were moderate (uncomfortable) in nature, and generally lasted 2 to 4 weeks. The most common side effects include temporary reactions at the treatment site such as tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. These side effects are consistent with other facial-injection procedures. See Section 14 for additional information on side effects seen in the clinical study.

Although most side effects will resolve with time, some side effects 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 **HA**).

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.

7. BENEFITS

What will it accomplish?

It will temporarily correct volume in the cheeks and cheek area that has been lost due to aging and will provide a smoother contour and more youthful appearance to the face.

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 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® VOLUMA™ 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 **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 into the cheek, your doctor will wait a few seconds to allow the **lidocaine** to take effect before moving forward with the rest of the treatment. JUVÉDERM® VOLUMA™ XC will be injected in small amounts over 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. An ice pack 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® VOLUMA™ XC injectable gel clinical study, immediately after injection subjects rated injection pain, on average, as a 3 on an 11-point scale where 0 is no pain and 10 is worst pain imaginable. JUVÉDERM® VOLUMA™ XC injectable gel 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 clinical trial the most common side effects were temporary reactions at the treatment site such as tenderness, swelling, firmness, and lumps/bumps. These side effects generally lasted 2 to 4 weeks. See Section 14 for additional information on side effects seen in the clinical study.

Your doctor will also tell you what to expect following treatment with JUVÉDERM® VOLUMA™ XC injectable gel. 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 place an ice pack over the swollen area. You should ask your doctor when makeup may be applied after your treatment.

(Continued on reverse side.)

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 clinical study, 82% of subjects received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired result.

Does the correction last forever?
No. While individual results may vary, in the clinical study, the results lasted up to 2 years in a majority of subjects treated with JUVÉDERM® VOLUMA™ XC. After this, **repeat injections** are usually needed to maintain your desired result.

11. ALTERNATIVE PROCEDURES

What other treatments are available to me?
Alternative treatments that are available to you to correct lost facial volume include surgical implants or injections of your own fat. You may discuss these treatment options with your doctor.

12. 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 skin, or
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

You may also contact the Allergan Product Surveillance line during normal business hours at 1-877-345-5372 to report any side effects.

13. CLINICAL STUDIES

How was the product studied?
To establish the safety and effectiveness of JUVÉDERM® VOLUMA™ XC injectable gel, 270 subjects (80% female and 20% male) were treated in the pivotal study. The study included patients with all Fitzpatrick Skin Types (lightest to darkest). To achieve subjects' desired results, a **touch-up** treatment was allowed 1 month after initial treatment. After 2 years or after correction had been lost, whichever was first, subjects were offered an optional repeat treatment.

The amount of JUVÉDERM® VOLUMA™ XC injectable gel used in the clinical study to achieve optimal outcomes ranged from 1.2 mL to 13.9 mL, with a median volume of 6.6 mL. In general, the amount of JUVÉDERM® VOLUMA™ XC used for the **touch-up** and repeat treatment was significantly less than the first treatment. For each patient the volume used was based on volume deficit and treatment goals.

To evaluate the safety of JUVÉDERM® VOLUMA™ XC injectable gel, subjects noted common side effects in 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 on restoring fullness to the cheek area, a 6-point scale ranging from 0 to 5 was used.

How was the product studied using cannula?
To evaluate treatment with JUVÉDERM® VOLUMA™ XC injectable gel using **cannula**, 60 subjects were treated in one cheek with a needle and the other cheek with a **cannula**. JUVÉDERM® VOLUMA™ XC with **cannula** was not studied in patients with darker skin types (Fitzpatrick Skin Types V and VI).

The median volume of JUVÉDERM® VOLUMA™ XC injectable gel was the same for the **cannula** and needle sides (median 2.0 mL) used in the clinical study to achieve optimal outcomes.

What did the clinical studies show?
In the pivotal clinical study, JUVÉDERM® VOLUMA™ XC injectable gel was found to effectively correct cheek shape and fullness.

- 86% of subjects had at least a 1-point improvement in their cheek fullness 6 months after treatment
- Subjects rated themselves as looking an average of 5 years younger 6 months after their last treatment
- More than 75% of subjects reported an improvement in their overall satisfaction with their facial appearance at 2 years after their last treatment

The pivotal clinical study showed that JUVÉDERM® VOLUMA™ XC injectable gel lasts up to 2 years in the majority of subjects.

In the clinical study using **cannula**, 93% of subjects had at least a 1-point improvement in their cheek fullness at 1 and 3 months after treatment in the **cannula**-treated cheek.

14. ADVERSE EFFECTS

What side effects were seen in the pivotal clinical study?
Most subjects in the clinical study experienced tenderness, swelling, firmness, and/or lumps/bumps at the injection site, as reported in their 30-day daily diary. These side effects were usually moderate in severity, did not require treatment, and generally lasted 2 to 4 weeks. Based on the pivotal clinical study, the likelihood of experiencing side effects after initial treatment with JUVÉDERM® VOLUMA™ XC is shown below in Table 1. These events were reported less often after repeat treatment.

Table 1. Side Effects After Initial Treatment in the Pivotal Study[a,b]

Side Effect	Likelihood of Experiencing Side Effect
Any Side Effect	98 out of 100 people (98%)
Tenderness	92 out of 100 people (92%)
Swelling	86 out of 100 people (86%)
Firmness	82 out of 100 people (82%)
Lumps/Bumps	81 out of 100 people (81%)
Bruising	78 out of 100 people (78%)
Pain	66 out of 100 people (66%)
Redness	66 out of 100 people (66%)
Discoloration	41 out of 100 people (41%)
Itching	39 out of 100 people (39%)

[a]Occurring in > 5% of subjects
[b]Based on 265 subjects who provided information about side effects after initial treatment.

What side effects were seen in the clinical study using cannula?
Most subjects in the clinical study experienced tenderness, firmness, swelling, and/or lumps/bumps at the injection site, as reported in their 30-day daily diary. These side effects were usually mild or moderate in severity, did not require treatment, and generally lasted 2 weeks. Based on this clinical study, the likelihood of experiencing side effects after treatment using a **cannula** with JUVÉDERM® VOLUMA™ XC is shown below in Table 2.

Table 2. Side Effects After Initial Treatment With Cannula[a]

Side Effect	Likelihood of Experiencing Side Effect
Any Side Effect	60 out of 60 people (100%)
Tenderness	55 out of 60 people (92%)
Firmness	50 out of 60 people (83%)
Swelling	49 out of 60 people (82%)
Lumps/Bumps	42 out of 60 people (70%)
Pain	40 out of 60 people (67%)
Bruising	36 out of 60 people (60%)
Redness	33 out of 60 people (55%)
Discoloration	22 out of 60 people (37%)
Itching	11 out of 60 people (18%)

[a]Based on 60 subjects who provided information about side effects after initial treatment with cannula.

What adverse events were seen in the pivotal clinical study?
Adverse events (any side effects to JUVÉDERM® VOLUMA™ XC that lasted longer than the 30-day daily diary, or side effects that occurred after 30 days) 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, swelling, and pain. Adverse events were seen more frequently in subjects who received a large volume of product and subjects who were older. Rarely, adverse events occurred weeks to months after the injection procedure.

What adverse events were seen in the clinical study using cannula?
Among the 60 subjects treated with JUVÉDERM® VOLUMA™ XC using a **cannula**, 2 subjects experienced 3 treatment-related adverse events (lumps and bumps on the needle cheek in one subject and plaque [dry, flaky, rough skin] on both the needle and **cannula** cheeks in another subject).

What side effects have been reported through voluntary postmarket surveillance of JUVÉDERM® VOLUMA™ XC use in and outside of the United States?
The most commonly reported adverse events were swelling, redness, bruising, pain, nodule, and inflammation.

- 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
- 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
- Inflammation generally occurred from the day of treatment to 2 months after injection. Treatment included antibiotics, steroids, and needle aspiration. Resolution of symptoms has been reported within 4 days

Additionally, there have been reports of allergic reaction, infection, skin discoloration, and blood vessel blockage.

- Allergic reaction generally occurred from immediately to 1 day after injection. Treatment included steroids, **hyaluronidase**, and antihistamines
- Infection generally occurred from immediately to 1 month after injection. Treatment included antibiotics, pain killers, antifungals, **hyaluronidase**, and antibacterial medicines
- Skin discoloration generally occurred from immediately to 1 month after injection. Treatment included antihistamines, **arnica**, **hyaluronidase**, **NSAIDs**, and steroids
- Blood vessel blockage generally occurred from immediately to 1 week after injection. Treatment included **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: acne, **abscess**, anxiety, swelling from reactive blood vessels, bleeding, depression, discomfort, dizziness, cyst, dry skin, product coming back out, flu-like symptoms, headache, herpes, increase or decrease in sensation, device migration, nausea, **necrosis**, scarring, shortness of breath, tissue hardening, vision abnormalities, vision loss, loss/lack of correction, unsatisfactory results, collection of blood outside of a blood vessel, varied injuries, drainage, overcorrection, cardiac complications, autoimmune disorder exacerbation, severe life-threatening allergic reaction, a layer of reactive tissue within the body that is infected around a device, blister, rash, swollen lymph node, passing out, spider vein, calcification, and deeper wrinkle.

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.

15. ADDITIONAL INFORMATION

What if I experience a problem?
If you believe that you have experienced a serious problem related to JUVÉDERM® VOLUMA™ 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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05/2023 022758 20079138