

About JUVÉDERM® VOLUMA™ XC for Chin 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

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 JUVÉDERM® VOLUMA™ XC, 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

Photonumeric—using numbers to rate pictures

Pigmentation disorder—a medical condition that results in a change in skin color

Primary study endpoint—the main measurement of success for the study

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

Subcutaneous and/or supraperiosteal—the layer under the skin, just above the bone, where JUVÉDERM® VOLUMA™ XC is injected

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 chin and surrounding area of the face for shaping of the chin.

3. INDICATION/INTENDED USE

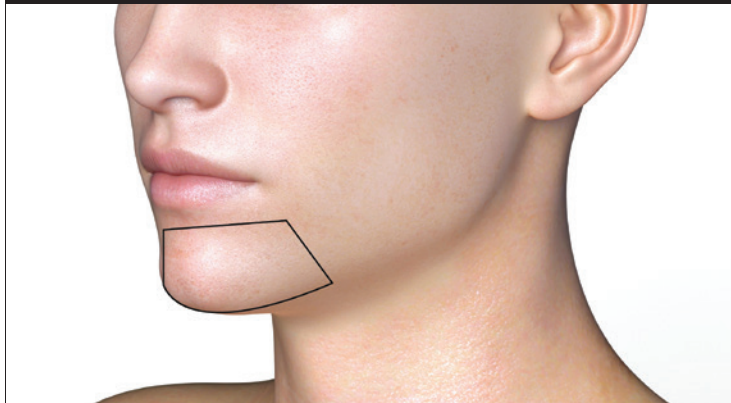
What is it for?

JUVÉDERM® VOLUMA™ XC is indicated for deep (**subcutaneous and/or supraperiosteal**) injection for augmentation of the chin region to improve the chin profile in adults over the age of 21.

What does it do?

JUVÉDERM® VOLUMA™ XC injectable gel is injected into the chin area to increase the chin projection. It temporarily adds volume to the chin area and results in an improved chin shape. Figure 1 shows the treatment areas for JUVÉDERM® VOLUMA™ XC for chin augmentation.

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



How is it used?

It is injected under the skin, just above the bone, into the chin area using a small needle or cannula (blunt tip needle).

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) or history or presence of multiple severe allergies. 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 22 years or over 80 years.
- Tell your doctor which areas of your face you would like to have treated. This product is intended for use in the chin and cheek (refer to the JUVÉDERM® VOLUMA™ XC Patient Label for Cheek 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.
- Loose skin of the chin, neck, or jaw could obscure the effects of JUVÉDERM® VOLUMA™ XC treatment in the chin region. Therefore, in the chin study, the device was not evaluated in subjects with significant loose skin of the chin, neck, or jaw.
- The effect of JUVÉDERM® VOLUMA™ XC injection into the chin on facial hair growth has not been studied.

6. RISKS

What are possible side effects?

In the clinical study, most side effects were mild (easily tolerated) in nature, and generally resolved in 2 to 4 weeks. The most common side effects include temporary reactions at the treatment site such as tenderness, firmness, swelling, pain, lumps/bumps, bruising, redness, itching, and discoloration. 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.

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 4 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, discoloration, and blood vessel blockage.

- Allergic reaction generally occurred from immediately to 1 day after injection. Treatment included steroids and antihistamines
- Infection generally occurred from immediately to 1 month after injection. Treatment included antibiotics, pain killers, antifungals, and antibacterial medicines
- Discoloration generally occurred from immediately to 1 month after injection. Treatment included antihistamines, **arnica**, **hyaluronidase**, **NSAIDs**, and steroids

(Continued on reverse side.)

What side effects have been reported through voluntary postmarket surveillance of JUVÉDERM® VOLUMA™ XC use in and outside of the United States? (continued)

- 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: **abscess**, anxiety, bleeding, depression, discomfort, dizziness, dry skin, extrusion, flu-like symptoms, headache, herpes, increase or decrease in sensation, migration, nausea, **necrosis**, scarring, shortness of breath, tissue hardening, vision abnormalities, loss/lack of correction, unsatisfactory results, varied injuries, drainage, overcorrection, cardiac complications, and deeper wrinkle.

7. BENEFITS

What will it accomplish?

It will temporarily add volume to the chin area and result in an improved chin shape.

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 chin area, 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 chin augmentation 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, firmness, swelling, and pain. These side effects generally resolved in 1 week. Other reported side effects included lumps/bumps, bruising, redness, itching, and discoloration. All side effects resolved within 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.

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 chin augmentation clinical study, 60% 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 chin augmentation clinical study, the results lasted up to 1 year in a majority of subjects (58%) 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 for chin augmentation 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 for chin augmentation, 182 subjects (89% female and 11% male) were treated. To achieve subjects' desired results, a **touch-up** treatment was allowed 1 month after initial treatment. After 1 year, 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 0.7 mL to 4.0 mL, with a median volume of 2.4 mL. In general, the amount of JUVÉDERM® VOLUMA™ XC used for the **touch-up** and repeat treatments 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 for chin augmentation, a 5-point scale ranging from 0 to 4 was used.

What did the clinical study show?

JUVÉDERM® VOLUMA™ XC injectable gel was found to effectively augment the chin.

- Based on 2D photo assessment by the doctor using the 5-point **photonumeric** Allergan Chin Retrusion Scale (ACRS), 56% of subjects had at least a 1-point improvement in their chin profile 6 months after treatment.
- Based on in-person live assessment by the doctor using the ACRS, 92% of subjects had at least a 1-point improvement in their chin profile 6 months after treatment.
- The following subjects did not meet the **primary study endpoint** of 50% of participants with at least a 1-point improvement in their chin profile 6 months after treatment based on the 2D photo assessment: those aged 51.5 years and older (46% of treated subjects showed improvement), those with darker skin (29%), and males (47%). However, satisfaction was still high among these subjects.
- More than 90% of subjects reported an improvement in their overall satisfaction with how their chin looked at 1 year after treatment.
- Most of the subjects (> 85%) reported satisfaction with how well their chin suits their face through 1 year after treatment.

The clinical study showed that the JUVÉDERM® VOLUMA™ XC injectable gel treatment in the chin lasts up to 1 year in the majority of subjects.

14. ADVERSE EFFECTS

What side effects were seen in the clinical study?

Most subjects in the clinical study experienced tenderness and/or firmness at the injection site, as reported in their 30-day daily diary. These side effects were usually mild in severity, did not require treatment, and generally resolved in 1 week. Side effects lasting 15 to 30 days were experienced by 35% of subjects, and severe side effects were experienced by 12% of subjects. Based on the clinical study, the likelihood of experiencing side effects after initial treatment with JUVÉDERM® VOLUMA™ XC in the chin area is shown below in Table 1. These events were reported less often after repeat treatment.

Table 1. Side Effects After Initial Treatment^{a,b}

| Side Effect | Likelihood of Experiencing Side Effect |
|-----------------|--|
| Any Side Effect | 92 out of 100 people (92%) |
| Tenderness | 82 out of 100 people (82%) |
| Firmness | 75 out of 100 people (75%) |
| Swelling | 69 out of 100 people (69%) |
| Pain | 63 out of 100 people (63%) |
| Lumps/Bumps | 60 out of 100 people (60%) |
| Bruising | 59 out of 100 people (59%) |
| Redness | 49 out of 100 people (49%) |
| Itching | 28 out of 100 people (28%) |
| Discoloration | 15 out of 100 people (15%) |

^aOccurring in > 5% of subjects.

^bBased on 181 subjects who provided information about side effects after initial treatment.

What adverse events were seen in the clinical study?

Adverse events (any side effects to JUVÉDERM® VOLUMA™ XC for chin augmentation reported by the doctors) were reported over the course of the study. The most common adverse events were redness and pain, which were reported in 2% of subjects (2 out of 100 people). Rarely, adverse events occurred weeks to months after the injection procedure. One subject had 3 treatment-related adverse events of injection-site swelling after initial/**touch-up** treatment that began 173 days, 248 days, and 252 days after treatment. These events of swelling resolved within 3 days with medication.

A total of 11 subjects experienced 14 serious adverse events (SAEs) after treatment with JUVÉDERM® VOLUMA™ XC for chin augmentation. Of the 14 SAEs, two (injection-site inflammation and injection-site cellulitis, which is a type of skin infection) were treatment related and occurred in the same subject. These SAEs were treated with medication. The inflammation lasted for 153 days and the cellulitis for 36 days.

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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