About JUVÉDERM® VOLUMA® XC to Improve Moderate to Severe Temple Hollowing

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 gel

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

Fitzpatrick Skin Type—a numerical scale used for classification of human skin color based on reaction to sunlight

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

Maintenance treatment—an additional treatment with JUVÉDERM® VOLUMA® XC that is given after the effects of the initial treatment start to wear off in order to maintain the desired aesthetic outcome

Necrosis—death of living tissue (skin)

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

Photonumeric—using numbers to rate in-person live assessments

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

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 smaller amount of dermal filler usually given approximately 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result

Vasodilators—medicines that open blood vessels

Visual Acuity—a measure of an individual's vision sharpness tested on a standardized eye chart at a distance

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. This results in a specialized, smooth, robust injectable gel that produces long-lasting, enduring aesthetic results in the treated area. JUVÉDERM® VOLUMA® XC is delivered by an injection into the temple area to improve moderate to severe temple hollowing.

3. INDICATION/INTENDED USE

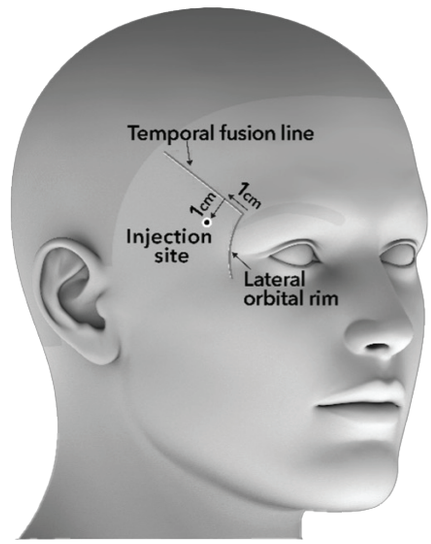
What is it for?

JUVÉDERM® VOLUMA® XC is indicated for the **supraperiosteal** injection to augment the temple region to improve moderate to severe temple hollowing in adults over the age of 21.

What does it do?

JUVÉDERM® VOLUMA® XC is injected directly in the temple area to improve moderate to severe temple hollowing. It temporarily adds volume to immediately lift and augment the shape, contour, and structure of the temple, creating a smooth transition from the cheekbone to the forehead, balancing a patient's overall facial shape. Figure 1 shows the treatment areas for JUVÉDERM® VOLUMA® XC to improve moderate to severe temple hollowing.

Figure 1. Treatment Area for JUVÉDERM® VOLUMA® XC to Improve Moderate to Severe Temple Hollowing



How is it used?

It is injected under the skin, just above the bone, into the temple area using a small 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 use of JUVÉDERM® VOLUMA® XC to improve moderate to severe temple hollowing.

- 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 **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 32 years or over 82 years.
- Tell your doctor which areas of your face you would like to have treated. This product is intended for use in the temple, cheek, and chin areas (refer to the JUVÉDERM® VOLUMA® XC Patient Label for Cheek Augmentation and Chin Augmentation). 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.

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6. RISKS

What are possible side effects?

In the clinical study, most side effects were mild (70.5%, 67 of 95 reported side effects) in nature (easily tolerated), and generally resolved in 3 days (60.0%, 57 of 95 reported side effects). The most common side effects include temporary reactions at the treatment site such as tenderness, firmness, swelling, pain, lumps/bumps, bruising, redness, itching, headache, 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.

Subjects were assessed on visual acuity and functionality after the completion of initial, touch-up, and maintenance treatments. 11 of the 156 subjects (7%) who received treatment had worsening of their visual acuity and 10 of the 156 subjects (6%) showed improvement. 5 of 36 subjects (14%) had improvement of their visual acuity and none of the subjects had worsening in visual acuity after maintenance treatment. The visual acuity remained the same for all other subjects post initial/touch-up and maintenance treatments. All events were evaluated by the investigators and not considered related to JUVÉDERM® VOLUMA® XC or the injection procedure.

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 one 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, skin 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
- 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, 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.

7. BENEFITS

What will it accomplish?

It will temporarily add volume to immediately fill and lift the temple area, providing more balanced facial proportions and a smooth, structured, facial contour.

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 another **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 temple 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 clinical study to improve moderate to severe temple hollowing, immediately after injection, subjects rated an average injection pain score of 1.3 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 pain after injection, tenderness to touch, redness, and firmness. These side effects generally resolved in 3 days (60%, 57 of 95 reported side effects). Other reported side effects included swelling, lumps/bumps, bruising, discoloration, and itching. Most side effects resolved within 2 weeks (93.7%, 89 of 95 reported side effects). The longest duration of side effects after initial treatment was 30 days for firmness. 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 improvement of moderate to severe temple hollowing clinical study, 65% of subjects received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired result.

Does the improvement last forever?

No. While individual results may vary, in the clinical study to improve moderate to severe temple hollowing, the results lasted up to 13 months in a majority of subjects (73%) treated with JUVÉDERM® VOLUMA® XC. After this, **maintenance treatments** 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 improve moderate to severe temple hollowing 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.

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13. CLINICAL STUDIES

How was the product studied?

To establish the safety and effectiveness of JUVÉDERM® VOLUMA® XC injectable gel for improvement of moderate to severe temple hollowing, 170 subjects (84% female and 16% male) received treatment as randomized (58 control and 112 treated). To achieve subjects' desired results, a **touch-up** treatment was allowed 1 month after initial treatment. After 13 months, subjects were offered an optional maintenance treatment.

The amount of JUVÉDERM® VOLUMA® XC injectable gel used in the clinical study to achieve optimal outcomes ranged from 0.4 mL to 8.0 mL for both temples, with a median volume of 3.65 mL. In general, the amount of JUVÉDERM® VOLUMA® XC used for the **touch-up** and **maintenance treatments** was less than that used for the initial treatment. For each patient the volume used was based on temple hollowing severity 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. Other evaluations of safety included vision assessments, pain assessments, and testing of jaw functionality. To evaluate the effectiveness of the product to improve moderate to severe temple hollowing, 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 be effective in improving moderate to severe temple hollowing.

- Based on in-person live assessment by the doctor using the 5-point **photonumeric** Allergan Temple Hollowing Scale, more than 80% of subjects (91 of 113 subjects) had at least a 1-point improvement in moderate to severe temple hollowing 3 months after treatment, and the improvements lasted for more than 1 year (73%, 66 of 90 subjects).
- Based on the in-person assessment by the doctor and subject using the 5-point Global Aesthetics Improvement Scale, more than 85% of the subjects (90 of 104 subjects) were improved or much improved in temple hollowing at 1 month after treatment, and improvements lasted for more than 1 year (72%, 65 of 90 subjects).
- More than 85% of subjects were satisfied with how balanced, well-proportioned, and symmetric their face looked 3 months after treatment.
- More than 80% of subjects were satisfied with how youthful their temples made them look and how well the shape of their temples complimented the shape of their face 3 months after treatment.
- More than 85% of the subjects reported satisfaction with how their temples looked in photos, in a mirror, in a side view, and under bright light 3 months after treatment.
- More than 87% of subjects were satisfied with how well their face appeared after temple treatment, with 68% satisfied with how fresh their face looked and 73% with how rested their face appeared 3 months after treatment.
- Subjects reported looking an average of 5 years younger, through 6 months after treatment.
- More than 85% of the subjects were satisfied with how natural the temple area looked and felt after treatment.
- More than 1 year after treatment, over 85% of the subjects were satisfied with the treatment and would recommend to a friend.
- More than 1 year after treatment, over 70% of the subjects said they would likely continue treatment.
- Maintenance treatment more than 1 year later produced similar results with approximately half the injection volume.

The clinical study showed that the JUVÉDERM® VOLUMA® XC injectable gel treatment for improvement of moderate to severe temple hollowing lasts up to 13 months in the majority of subjects.

14. ADVERSE EFFECTS

What side effects were seen in the clinical study?

Most subjects in the clinical study experienced pain, tenderness, and/or firmness at the injection site, as reported in their electronic diary. These side effects were usually mild in severity, did not require treatment, and generally resolved within 3 days (57 of 95 reported side effects, 60.0%). Side effects lasting 15 to 30 days were experienced by less than 6% of subjects (6 of 95 reported side effects), and severe side effects were experienced by less than 3% of subjects (3 of 95 reported side effects). Based on the clinical study, the likelihood, severity, and duration of the side effects after initial treatment with JUVÉDERM® VOLUMA® XC in the temple is shown below in Table 1 and Table 2. These events were reported less often after **touch-up** and **maintenance injections**.

Table 1. Likelihood and Severity of Side Effects After Initial Treatment[a,b]

Side Effect	Likelihood of Experiencing Side Effect	Maximum Severity of Side Effect		
		Mild	Moderate	Severe
Any Side Effect	59 out of 100 people (59%)	42%	16%	2%
Pain	51 out of 100 people (51%)	38%	11%	2%
Tenderness	50 out of 100 people (50%)	43%	6%	1%
Redness	41 out of 100 people (41%)	34%	6%	1%
Firmness	38 out of 100 people (38%)	34%	4%	1%
Swelling	30 out of 100 people (30%)	26%	4%	0%
Lumps/Bumps	26 out of 100 people (26%)	23%	3%	0%
Bruising	16 out of 100 people (16%)	15%	1%	0%
Headache	9 out of 100 people (9%)	7%	2%	1%
Discoloration	7 out of 100 people (7%)	6%	1%	0%

[a] Occurring in > 5% of subjects.
[b] Based on 161 subjects who provided information about side effects after initial treatment.

Table 2. Duration of Side Effects After Initial Treatment[a,b]

Side Effect	Maximum Duration of Side Effect			
	Less than or equal to 3 Days	4 to 7 Days	8 to 14 Days	15 to 30 Days
Any Side Effect	35%	12%	8%	4%
Pain	38%	9%	4%	1%
Tenderness	34%	10%	4%	1%
Redness	34%	4%	2%	1%
Firmness	29%	4%	3%	2%
Swelling	21%	5%	4%	1%
Lumps/Bumps	21%	4%	1%	1%
Bruising	11%	3%	2%	0%
Headache	6%	0%	0%	0%
Discoloration	6%	1%	0%	0%

[a] Occurring in > 5% of subjects.
[b] Based on 161 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 to improve moderate to severe temple hollowing reported by the doctors) were reported over the course of the study. The most common adverse events were pain in jaw, reported in 6% of subjects (10 of 165 subjects), and headache, reported in 5% of subjects (8 of 165 subjects). No adverse events occurred more than 30 days after the injection procedure.

Treatment-related adverse events occurred within 1 week after treatment for 16% of subjects (27 of 165 subjects) and resolved without requiring treatment within 1 week for 15% of subjects (25 of 165). There were 7 treatment-related adverse events that began 1 week after treatment affecting 3% of the subjects (5 of 165), which were injection site mass, pain in jaw, headache, and discomfort in chewing. There were no treatment-related adverse events that began more than 30 days after treatment.

There were 6 treatment-related adverse events for 4 subjects (2%, 4 of 165 subjects) that lasted longer than 30 days, including mild discomfort while opening the mouth that lasted 42 days, mild injection site mass in the left temple that lasted 56 days, mild injection site pain in both temples that lasted 32 days, and mild injection site mass in both temples that lasted 66 days. All the treatment-related adverse events lasting longer than 30 days resolved without intervention. There were no treatment-related serious adverse events observed in the study.

There were fewer adverse events reported by subjects after maintenance treatment. The majority of the adverse events were mild (49 of 51 total reported adverse events, 96%) and resolved within 1 week (44 of 51 total reported adverse events, 86%).

Analysis of adverse events in subgroups of **Fitzpatrick skin type**, gender, age, and ethnicity demonstrated that JUVÉDERM® VOLUMA® XC is safe in all subgroups.

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. You may also report the occurrence of any adverse events to the Food and Drug Administration through the MedWatch Program: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

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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