About JUVÉDERM® VOLUX™ XC

Before beginning your treatments, please review this important information.

1. GLOSSARY

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

Abscess—a swollen lump filled with pus

Anesthetic—a substance that reduces sensitivity to pain

BDDE—a small biodegradable compound added to crosslink the gel

Cannula—a thin metal tube with a blunt tip

Hyaluronic acid (HA)—a polysaccharide (sugar) that is naturally in the body. It keeps skin hydrated, moisturized, and soft. JUVÉDERM® VOLUX™ XC injectable gel is 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

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

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

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 JUVÉDERM® VOLUX™ XC usually given about 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired aesthetic outcome

VYCROSS® technology—a unique manufacturing process that creates crosslinked HA that results in the specialized smooth gel filler

2. PRODUCT DESCRIPTION

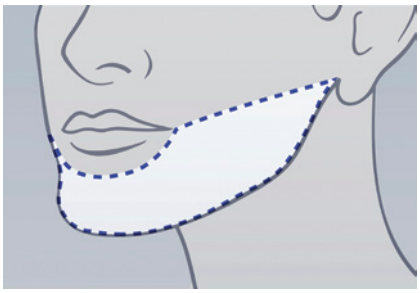
What is it?

JUVÉDERM® VOLUX™ XC injectable gel is a smooth, 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 skin that retains moisture. JUVÉDERM® VOLUX™ XC injectable gel is manufactured using **VYCROSS® technology**, during which, a small amount of the compound **BDDE** is added to crosslink the **HA** in the gel. This results in a specialized and smooth injectable gel that produces jawline definition in the treated area.

How does it work?

JUVÉDERM® VOLUX™ XC is a clear gel that is injected directly in the jaw area using an ultrafine needle or **cannula** to improve jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition (treatment area is depicted in Figure 1). The product provides volume to augment the shape and structure of the lower face, creating a smooth contour along the jawline and/or helping to reduce the appearance of jowls. The **lidocaine** in the gel improves the comfort of the injection by reducing sensitivity to pain.

Figure 1. Treatment Area for Jawline Definition



3. CONTRAINDICATIONS

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

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

- You have severe allergies, marked by a history of severe reactions (anaphylaxis), or a history or presence of multiple severe allergies. Use may result in an allergic reaction.
- You are allergic to **lidocaine**. Use may result in an allergic reaction.
- You have previous experience with allergic reactions to **HA** fillers. Use may result in an allergic reaction.

4. WARNINGS

What warnings should my doctor advise me about?

To help you understand the treatment risks, your doctor should discuss the following:

- One of the risks of using dermal fillers is the 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. Most of these events are irreversible.
- If you have changes in your vision, 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), white appearance of the skin, or unusual pain during or shortly after treatment, you should notify your health care practitioner immediately.
- The use of JUVÉDERM® VOLUX™ XC where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of JUVÉDERM® VOLUX™ XC where these are present could delay healing or make your skin problems worse.
- The effectiveness of removal of any dermal filler has not been studied.

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 to help avoid unsatisfactory results and complications:

- Avoid applying makeup for 12 hours after treatment.
- Minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages 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 to have laser treatment, chemical peel, or any other procedure after treatment with JUVÉDERM® VOLUX™ XC. There is a possible risk for an inflammatory reaction at the treatment site.
- Tell your doctor which areas of your face you would like to have treated. This product is intended for use in the jaw area (treatment area is depicted in Figure 1). The safety and effectiveness for treatment in other areas of the body have not been established in controlled, clinical studies.
- Tell your doctor about any medications you are taking. You may have a greater risk of developing an infection if you use JUVÉDERM® VOLUX™ XC while taking any medication that reduces your body's natural defense system. This includes medicines to treat HIV and AIDS, autoimmune diseases such as rheumatoid arthritis and Crohn's disease, chemotherapy for cancer, and steroids like prednisone. Use may result in an increased risk for infection.
- Tell your doctor if you are pregnant or breastfeeding. The safety for use during pregnancy or in women who are breastfeeding has not been studied.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of JUVÉDERM® VOLUX™ 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® VOLUX™ 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 have already been injected with dermal fillers in the same area as the one(s) you are about to be treated for. This information helps your doctor decide when and whether you should get treatment with JUVÉDERM® VOLUX™ XC.

6. CLINICAL STUDY

How was the product studied?

To establish the safety and effectiveness of JUVÉDERM® VOLUX™ XC injectable gel for improving jawline definition, 156 participants from the treatment group received injections of the product into the jaw area at the beginning of the study, and 42 participants from the control group received injections 6 months later. To achieve the desired aesthetic outcome, a **touch-up** treatment was allowed 1 month after initial treatment. After 1 year, participants were offered a **maintenance treatment**.

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The amount of JUVÉDERM® VOLUX™ XC used in the clinical study to achieve desired aesthetic outcomes in the treatment group ranged from 1.0 mL to 9.3 mL, with a median volume of 6.8 mL for initial and touch-up treatment combined. In general, the amount of JUVÉDERM® VOLUX™ XC used for the **touch-up** and **maintenance treatments** was less than the first treatment.

To evaluate the safety of JUVÉDERM® VOLUX™ XC injectable gel, participants noted common side effects in daily diaries. Side effects were also reported by doctors based on office visits with each participant. These office visits included discussing any symptoms or complaints with the participants and assessing the definition of the jawline. To evaluate the effectiveness of the product for improving jawline definition and overall aesthetic appearance, 5-point scales were used. Participants used questionnaires to rate satisfaction with their lower face and jawline and the appearance of marionette lines after treatment.

7. BENEFITS

What will it accomplish?
The results of the JUVÉDERM® VOLUX™ XC clinical study showed that the product temporarily improves jawline definition.

What did the clinical study show?
JUVÉDERM® VOLUX™ XC injectable gel was found to effectively improve jawline definition. The clinical study showed that the improvement lasted for 1 year in the majority of participants.

The study doctors reported the following:

- At 6 months, 70% (102/146) of participants in the treatment group showed improvement in jawline definition; 61% (84/137) of participants in the treatment group showed long-lasting results through 1 year. At 6 months, 39% (18/146) of participants in the control group showed improvement in jawline definition; there was no control group result at 12 months since the control participants were given the option to get the treatment at 6 months.

The effectiveness of JUVÉDERM® VOLUX™ XC for jawline definition determined by the study doctor within the different subgroups at 6 months were analyzed and any differences observed within the subgroups were not considered statistically significant (Table 1).

Table 1: Effectiveness of JUVÉDERM® VOLUX™ XC for Jawline Definition by Different Subgroups at 6 Months

Subgroup	Treatment Participants with Improvement in Jawline Definition (%)
Male	78.6% (11/14)
Female	68.9% (91/132)
≤ Median Age (59)	76.1% (54/71)
> Median Age (59)	64.0% (48/75)
Fitzpatrick Skin Phototype I/II	62.7% (32/51)
Fitzpatrick Skin Phototype III/IV	72.0% (54/75)
Fitzpatrick Skin Phototype V/VI	80.0% (16/20)
Needle Only	66.7% (52/78)
Cannula	73.5% (50/68)

Treatment group participants reported the following:

- 74% saw an overall aesthetic improvement through 1 year after treatment
- 82% were satisfied with the appearance of their lower face and jawline through 1 year
- 82% were satisfied with how sculpted (well-defined) their jawline looked at 6 months compared with 12% before treatment
- 71% were satisfied with how smooth their lower face looked (no jowls or skin folds) at 6 months compared with 8% before treatment
- 73% were satisfied with how nice their lower face looked at 6 months compared with 9% before treatment

8. RISKS

What side effects were seen in the clinical study?
Participants reported side effects in 30-day daily diaries. Adverse events (AE) could also be reported by doctors at any time throughout the study.

Based on the clinical study, the likelihood of experiencing side effects after JUVÉDERM® VOLUX™ XC injectable gel is shown below in Table 2. Participants in the clinical study experienced side effects such as tenderness, lumps/bumps, pain, swelling, firmness, bruising, redness, itching, and discoloration at the injection sites, 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 effect on daily activities) in severity. Most of these side effects went away on their own within 2 weeks. A total of 35% of the side effects lasted up to 30 days. Participants also reported similar side effects after the **maintenance treatment**.

Table 2: Side Effects After First Treatment[a,b]

Side Effects	Likelihood of Experiencing Side Effect
Any Side Effect	85 out of 100 people (85%)
Tenderness	80 out of 100 people (80%)
Lumps/Bumps	79 out of 100 people (79%)
Pain	78 out of 100 people (78%)
Swelling	78 out of 100 people (78%)
Firmness	74 out of 100 people (74%)
Bruising	69 out of 100 people (69%)
Redness	68 out of 100 people (68%)
Itching	33 out of 100 people (33%)
Discoloration	33 out of 100 people (33%)

[a] Occurred in > 5% of participants.
[b] Based on the 196 participants treated with JUVÉDERM® VOLUX™ XC who provided information about side effects after their initial treatment.

What adverse events were seen in the clinical study?
Adverse events were reported by study doctors at any time throughout the study. After treatment with JUVÉDERM® VOLUX™ XC, 16 participants (8.1%, 16/198) experienced 20 treatment-related adverse events, with the most common being trouble chewing (2.0%, 4/198), lumps/bumps (1.5%, 3/198), and bruising (1.0%, 2/198). Other adverse events included injection site hypersensitivity (0.5%, 1/198), injection site pain (0.5%, 1/198), injection site swelling (0.5%, 1/198), injection site infection (0.5%, 1/198), oral herpes (0.5%, 1/198), movement difficulty and pain of the jaw joint and muscles (0.5%, 1/198), muscle tightness (0.5%, 1/198), muscle twitching (0.5%, 1/198), and headache (0.5%, 1/198). There were 15 mild and 5 moderate adverse events. The severity and duration of all treatment-related adverse events (from both the treatment and control groups) are summarized in Table 3. Similar adverse events were experienced by 3 participants (3.4%, 3/87) after **maintenance treatment**. Most of these adverse events were mild and went away on their own within 1 week. The treatment-related adverse events lasting longer than 30 days and with a delayed onset (> 30 days) are summarized in Table 4 and Table 5.

Table 3: Severity and Duration of Treatment-Related Adverse Events in the Treated Period (JUVÉDERM® VOLUX™ XC Treated Population)

	Participants (N=198) n (%)	Treatment-Related Adverse Events
Severity		
Total	16 (8.1%)	20
Mild	12 (6.1%)	15
Moderate	4 (2.0%)	5
Severe	0 (0.0%)	0
Duration		
Total	16 (8.1%)	20
≤ 7 Days	10 (5.1%)	13
8-14 Days	0 (0.0%)	0
15-30 Days	0 (0.0%)	0
> 30 Days	7 (3.5%)	7
Ongoing	0 (0.0%)	0

N: number of participants (from both control and treatment groups) who received initial treatment.
n: number of participants with at least one treatment-related AE.

Table 4: Treatment-Related Adverse Events with Duration Greater than 30 Days in the Treated Period (JUVÉDERM® VOLUX™ XC Treated Population)

AE	Severity	Time to Onset (Days after last treatment)	Duration (Days)	Outcome
Injection site nodule	Mild	4	176	Recovered/ Resolved
Injection site mass	Mild	1	163	Recovered/ Resolved
Injection site nodule	Mild	13	48	Recovered/ Resolved
Injection site hypersensitivity reaction	Moderate	17	118	Recovered/ Resolved
Injection site nodule	Mild	2	106	Recovered/ Resolved
Injection site nodule	Moderate	76	80	Recovered/ Resolved
Muscle twitching	Mild	8	33	Recovered/ Resolved

Table 5: Treatment-Related Adverse Events with Onset Days Greater than 30 Days After Last Treatment (JUVÉDERM® VOLUX™ XC Treated Population)

AE	Severity	Time to Onset (Days after last treatment)	Duration (Days)	Outcome
Injection site swelling	Mild	251	6	Recovered/ Resolved
Injection site nodule	Moderate	76	80	Recovered/ Resolved

The incidence of treatment-related adverse events in different subgroups is summarized in Table 6.

Table 6: Treatment-Related Adverse Events by Different Subgroups

Subgroup	Participants (%)	Events
Total Treatment-Related Adverse Events (N=198)	16 (8.1%)	20
≤ Median Volume (N=103)	12 (11.7%)	15
> Median Volume (N=95)	4 (4.2%)	5
Fitzpatrick Skin Phototype I/II (N=67)	3 (4.5%)	4
Fitzpatrick Skin Phototype III/IV (N=104)	8 (7.7%)	11
Fitzpatrick Skin Phototype V/VI (N=27)	5 (18.5%)	5
Needle Only (N=106)	10 (9.4%)	11
Cannula (N=92)	6 (6.5%)	9
Male (N=22)	1 (4.5%)	1
Female (N=176)	15 (8.5%)	19
≤ Median Age (59) (N=99)	7 (7.1%)	9
> Median Age (59) (N=99)	9 (9.1%)	11

N: numbers of participants in each group.

What other safety assessments were performed in the study?
The study included other safety measures where participants' jaw function, facial sensation, pronunciation, and vision were assessed before and after JUVÉDERM® VOLUX™ XC treatment. The results of these tests demonstrated that there were no changes in these functions after JUVÉDERM® VOLUX™ XC treatment.

What are other possible adverse events?
As with all skin injection procedures, there is a risk of infection.

Although most side effects will resolve within 30 days, some side effects may persist longer. Your doctor may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase**.

What side effects have been reported through voluntary postmarket surveillance of JUVÉDERM® VOLUX™ XC use outside of the United States?
The most commonly reported adverse events were the same as those reported by participants in the clinical study, such as lumps/bumps, swelling, redness, pain, itching, bruising, and discoloration. Additionally, there have been reports of nodules, inflammation, **abscess**, loss or lack of improvement, infection, allergic reaction, collection of blood outside of a blood vessel, gel migration, blood vessel blockage, increase or decrease in sensation, and cyst.

Treatments for adverse events included antibiotics, anti-inflammatory drugs, pain relievers, antiseptics, antihistamines, anti-stress and sleeplessness drugs, anti-swelling drugs, antithrombotics, blood thinners, calcium supplements, cold compress, drainage, **hyaluronidase**, hair growth stimulators, massage, muscle relaxants, proton-pump inhibitors (used for treatment of stomach acids), rectal ointment, steroids, surgery, sedatives, ultrasound, and Vitamin B.

9. BEFORE PROCEDURE INFORMATION

What happens in the office before the procedure?
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 you are an appropriate candidate for JUVÉDERM® VOLUX™ XC injectable gel and review what to expect during and after treatment, including possible side effects. Your doctor will also examine your jaw area. 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.

10. 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® VOLUX™ 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 ensure that the product integrates into the skin and is evenly distributed for a smooth appearance. 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. In the JUVÉDERM® VOLUX™ XC clinical study, immediately after the injection, treatment group participants reported a median pain score of 2 on an 11-point scale where 0 is no pain and 10 is worst pain imaginable. JUVÉDERM® VOLUX™ 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.

11. AFTER PROCEDURE INFORMATION

What should I expect following the procedure?
In the JUVÉDERM® VOLUX™ XC clinical study, the most common side effects were temporary responses at the treatment site, such as tenderness, lumps/bumps, pain, swelling, firmness, bruising, redness, itching, and discoloration. These side effects usually lasted 2 weeks or less. A total of 35% of the side effects lasted up to 30 days. See Section 8 for additional information on side effects seen in the clinical study.

Your doctor will also tell you what to expect following JUVÉDERM® VOLUX™ XC injectable gel. Within the first 24 hours, you should minimize strenuous exercise, exposure to extensive sun or heat, and alcoholic beverages. 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 results?
You should discuss your treatment goals and plan with your doctor. In the clinical study, 83% of participants treated with JUVÉDERM® VOLUX™ XC received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired aesthetic outcome. Among the 141 participants who completed the follow-up period, 87 participants (62%, 87/141) received **maintenance treatment** at 1 year.

Do the results last forever?
No. **Hyaluronic acid** fillers like JUVÉDERM® VOLUX™ XC are not permanent. The clinical study followed patients for one year and showed that the majority of patients (61%, 84/137) maintained their results for that one-year timeframe.

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 the skin
4) Unusual pain during or shortly after treatment

Be sure to 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

13. ADDITIONAL INFORMATION

If you believe that you have experienced a serious problem related to JUVÉDERM® VOLUX™ 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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