About JUVÉDERM® VOLBELLA™ XC

JUVÉDERM®
VOLBELLA™ 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

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

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® 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 medicines, such as aspirin or ibuprofen

Perioral—the area (skin) around the mouth and lips

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

Touch-up—an additional injection of a small amount of dermal filler usually given about 2 weeks to 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result

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® VOLBELLA™ 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 body. The role of **HA** in the skin is to deliver nutrients and help the skin retain its natural moisture and softness. JUVÉDERM® VOLBELLA™ XC injectable gel is manufactured using **VYCROSS® technology** to give a specialized smooth-gel filler that produces long-lasting results at the treatment site.

How does it work?

JUVÉDERM® VOLBELLA™ XC is a crystal-clear gel that is injected directly into and around the lips using an ultrafine needle to temporarily plump the lips for lip enhancement and to smooth the appearance of lines around the mouth in adults over the age of 21. The **lidocaine** in the gel improves the comfort of the injection by reducing sensitivity to pain.

3. CONTRAINDICATIONS

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

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

- You have severe allergies, marked by a history of severe reactions (anaphylaxis) or history or presence of multiple severe allergies. Use may result in an allergic reaction.
- You are allergic to **lidocaine** or to the proteins used to make the **HA** in JUVÉDERM® VOLBELLA™ XC (Gram-positive bacterial proteins). Use may result in an allergic reaction.

4. PRECAUTIONS

What precautions should my doctor advise me about?

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications:

- Minimize strenuous exercise and exposure to extensive sun or heat within the first 24 hours following treatment. Exposure to any of these may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are using any medication that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may increase bruising or bleeding at the injection site.
- Tell your doctor if you are planning laser treatment, chemical peeling, or any other procedure after treatment with JUVÉDERM® VOLBELLA™ XC. There is a possible risk of 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 lips and **perioral** area. The safety and effectiveness for treatment in other areas have not been established in controlled, clinical studies.
- Tell your doctor if you are on therapy used to decrease the body's immune response. Use may result in an increased risk of infection.
- Tell your doctor if you are pregnant or breastfeeding. The safety for use during pregnancy, 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® VOLBELLA™ 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® VOLBELLA™ XC in patients with a history of **pigmentation disorders** has not been studied. Use in these patients may result in changes in pigmentation.

5. CLINICAL STUDY

How was the product studied?

To establish the safety and effectiveness of JUVÉDERM® VOLBELLA™ XC for improving lip fullness and smoothing the appearance of lines around the mouth, 168 subjects received treatment with JUVÉDERM® VOLBELLA™ XC, and 56 subjects received treatment with another dermal filler. To achieve subjects' desired results, a **touch-up** treatment was allowed 1 month after initial treatment. After 1 year, subjects were offered a **repeat injection**.

The amount of JUVÉDERM® VOLBELLA™ XC used in the clinical study to achieve optimal outcomes ranged from 0.5 mL to 6.0 mL, with a median volume of 2.6 mL. In general, the amount of JUVÉDERM® VOLBELLA™ XC used for the **touch-up** and **repeat injection** was less than the first treatment. For each subject, the volume used was based on their desired results.

To evaluate the safety of JUVÉDERM® VOLBELLA™ 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 the appearance of their lips and **perioral** area. To evaluate the effectiveness of the product for lip enhancement, a 5-point scale was used. A 4-point scale was used to evaluate the effectiveness of the product for smoothing lines around the mouth. A 5-point scale was used to evaluate overall aesthetic improvement.

6. BENEFITS

What will it accomplish?

The results of the JUVÉDERM® VOLBELLA™ XC clinical study showed that the product temporarily improves lip fullness and smooths the appearance of lines around the mouth.

What did the clinical study show?

JUVÉDERM® VOLBELLA™ XC was found to effectively increase lip fullness and smooth the appearance of lines around the mouth. The clinical study showed that JUVÉDERM® VOLBELLA™ XC lasts through 1 year in the majority of subjects.

The study doctors reported:

- 80% of subjects had at least a 1-point improvement in lip fullness 3 months after treatment
- 62% of subjects had at least a 1-point improvement in lip fullness 1 year after treatment
- Over 60% of subjects had at least a 1-point improvement in the appearance of lines around the mouth through 1 year after treatment
- Overall aesthetic improvement was seen in 93% of subjects at 3 months after treatment and 59% of subjects at 1 year after treatment

Subjects reported:

- Improvement through 1 year in satisfaction with their lips and lip lines based on satisfaction questionnaires
- Over 90% thought their lips looked and felt natural for 1 year after treatment

7. RISKS

What side effects were seen in the clinical study?

Subjects reported side effects in 30-day daily diaries. If these side effects lasted longer than 30 days, they were reported as adverse events. Adverse events could also be reported by doctors at any time throughout the study.

Based on the clinical study, the likelihood of experiencing side effects after treatment with JUVÉDERM® VOLBELLA™ XC is shown below in Table 1. A majority of subjects in the clinical study experienced a side effect, such as swelling, tenderness, bruising, firmness, lumps/bumps, redness, or pain at the injection site, as reported in their 30-day daily diaries. These side effects were usually mild (easily tolerated) or moderate (uncomfortable) in severity, although some subjects experienced severe side effects (incapacitating). Most of these side effects went away on their own within 30 days. Occasionally, some subjects experienced side effects that lasted longer than 30 days.

(Continued on reverse side.)

What side effects were seen in the clinical study? (continued)

Table 1. Side Effects After Treatment[a,b]	
Side Effect	**Likelihood of Experiencing Side Effect**
	JUVÉDERM® VOLBELLA™ XC
Any Side Effect	97 out of 100 people (97%)
Swelling	93 out of 100 people (93%)
Tenderness	90 out of 100 people (90%)
Bruising	89 out of 100 people (89%)
Firmness	89 out of 100 people (89%)
Lumps/Bumps	88 out of 100 people (88%)
Redness	83 out of 100 people (83%)
Pain	81 out of 100 people (81%)
Discoloration	42 out of 100 people (42%)
Itching	31 out of 100 people (31%)
Dryness	5 out of 100 people (5%)

[a]Occurring in > 5% of subjects.

[b]Based on the 168 subjects treated with JUVÉDERM® VOLBELLA™ XC who provided information about side effects after their initial treatment.

What adverse events were seen in the clinical study?

Adverse events (any side effects that lasted longer than the 30-day daily diary, or adverse events reported by doctors at any time throughout the study) were reported over the course of the study. After treatment with JUVÉDERM® VOLBELLA™ XC, the most common adverse events for subjects were the same as those reported in the daily diary, such as lumps/bumps, bruising, pain, firmness, and swelling. Most of these adverse events were mild and went away on their own within 30 days.

In the clinical study, 7 subjects had lumps/bumps or swelling that occurred weeks to months after treatment. All of these adverse events were mild or moderate. An over-the-counter pain reliever or an antibiotic was given for the swelling, and no medication was given for the lumps/bumps. All of these events went away without any long-term effects.

Subjects experienced similar adverse events after **repeat injection**.

What are other possible adverse events?

As with all skin-injection procedures, there is a risk of infection.

One of the risks with using this product is 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.

Although most side effects will resolve within 30 days, some side effects may persist longer. Your physician may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase** (an enzyme that breaks down **HA**).

What side effects have been reported through voluntary postmarket surveillance of JUVÉDERM® VOLBELLA™ 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 5 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 3 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 3 days after injection. Treatment included antihistamines, **arnica**, **hyaluronidase**, **NSAIDs**, and steroids
- Blood vessel blockage generally occurred from immediately to 3 days 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, cardiac complication, deeper wrinkle, 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, and overcorrection.

8. BEFORE PROCEDURE INFORMATION

What happens in the office before the injection?

Note that each doctor may have a unique process for assessing and treating patients. The following is an example of what you would likely experience with a typical procedure. Before the injection procedure, your doctor will ask you questions about your medical history, as well as your treatment goals. Your doctor will discuss whether you are an appropriate candidate for JUVÉDERM® VOLBELLA™ XC and review what to expect during and after treatment, including possible side effects. Your doctor will also examine your lips and/or 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, your doctor will wait a few seconds to allow the **lidocaine** to take effect before moving forward with the rest of the treatment. JUVÉDERM® VOLBELLA™ XC will be injected in small amounts into the treatment area until the desired aesthetic outcome is achieved. Your doctor may massage the treatment area gently to assure that the product integrates in 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® VOLBELLA™ XC clinical study, immediately after the injection, subjects rated pain, on average, as a 3 on an 11-point scale where 0 is no pain and 10 is worst pain imaginable. JUVÉDERM® VOLBELLA™ XC contains **lidocaine** to reduce injection site pain. Your doctor may also choose to numb (anesthetize) the treatment area with a **topical** or injected numbing agent to further minimize discomfort.

10. AFTER PROCEDURE INFORMATION

What should I expect following the procedure?

In the JUVÉDERM® VOLBELLA™ XC clinical trial, the most common side effects were temporary responses at the treatment site such as swelling, tenderness, bruising, firmness, and lumps/bumps. These side effects usually lasted 2 weeks or less. See Section 7 for additional information on side effects seen in the clinical study.

Your doctor will also tell you what to expect following treatment with JUVÉDERM® VOLBELLA™ XC. Within the first 24 hours, you should minimize strenuous exercise and exposure to extensive sun or heat. Exposure to any of the above may increase temporary redness, swelling, and/or itching at the injection site. If there is swelling, you may need to place an ice pack over the swollen area. You should ask your doctor when makeup may be applied after your treatment.

Will I need more than one treatment to achieve my desired results?

You should discuss your treatment goals and plan with your doctor. In the clinical study, 62% of subjects treated with JUVÉDERM® VOLBELLA™ XC received a **touch-up** treatment 1 month after initial treatment in order to achieve the desired results.

Do the results last forever?

No. While individual results may vary, in the clinical study, the results lasted for 1 year in over 60% of subjects treated with JUVÉDERM® VOLBELLA™ XC. After this, **repeat injections** are usually needed to maintain your desired result.

11. WHEN TO CALL YOUR DOCTOR

When should I call my doctor?

Call your doctor immediately if you have:

1) Changes in your vision
2) Signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion)
3) White appearance of the skin
4) Unusual pain during or shortly after treatment

Be sure to call your doctor if you have:

1) Significant pain away from the injection site
2) Any redness and/or visible swelling that lasts for more than a few days
3) Any side effect that occurs weeks or months after treatment
4) Any other symptoms that cause you concern

12. ADDITIONAL INFORMATION

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