

# JUVÉDERM® VOLBELLA® XC for Undereye Hollows

## Patient Information Labeling

### About 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 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

**Cannula**—a thin metal tube with a blunt tip

**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

**Under-eye hollows**—depressed, sunken, or hollow area under the eye

**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** 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-gel filler. Results at the treatment

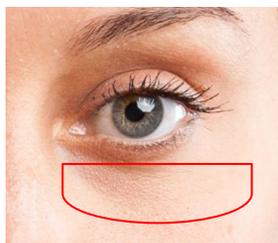
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site are long-lasting for up to 1 year with optimal improvement (over half of the subjects in the clinical study received a **touch-up** treatment).

### How does it work?

JUVÉDERM® VOLBELLA® XC is a crystal-clear gel that is injected directly into the **under-eye hollows** (see Figure 1) using an ultrafine needle or cannula to improve the appearance of **under-eye hollows** in adults over the age of 21. The **lidocaine** in the gel reduces discomfort from the injection.

Figure 1. Treatment area for JUVÉDERM® VOLBELLA® XC



### 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**, use may result in an allergic reaction.
- If 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 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.
- The use of JUVÉDERM® VOLBELLA® XC where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of JUVÉDERM® VOLBELLA® XC where these are present could delay healing or make your skin problems worse.

### 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:

- 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,

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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 **under-eye hollows** area. The safety and effectiveness for treatment in areas other than the lips, **perioral area**, and **under-eye hollows** have not been established in controlled clinical studies.
- Tell your doctor about any medicines you are taking. You may have a greater risk of developing an infection if you use JUVÉDERM® VOLBELLA® 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 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.

## 6. CLINICAL STUDY

### How was the product studied?

To establish the safety and effectiveness of JUVÉDERM® VOLBELLA® XC injectable gel for the treatment of **under-eye hollows**, 105 subjects received treatment. 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**.

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 **under-eye hollow** area. To evaluate the effectiveness of the product for the treatment of **under-eye hollowing** a 5-point scale was used.

## 7. BENEFITS

### What will it accomplish?

Treatment with JUVÉDERM® VOLBELLA® XC will add volume to your under-eye area to improve the appearance of **under-eye hollowing**.

### What did the clinical study show?

JUVÉDERM® VOLBELLA® XC was found to effectively improve the appearance of **under-eye hollowing**. The clinical study showed that improvement lasts through 1 year in the majority of subjects.

The study doctors reported:

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- 83% of subjects had at least a 1-point improvement in their **under-eye hollows** at 3 months after treatment
- 73% of subjects had at least a 1-point improvement in their **under-eye hollows** at 1 year after treatment

Subjects reported:

- 90% of subjects were satisfied through 1 year after treatment
- 80% of subjects were a little or not at all bothered by how tired or old the under eye area looked at 3 months compared to 15% and 30% before treatment, respectively
- 84% of subjects rated improvement in overall appearance at 3 months and 79% at 1 year after treatment

### 8. RISKS

#### What side effects were seen in the clinical study?

Subjects reported side effects in 30-day daily diaries. 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 tenderness, bruising, swelling, lumps/bumps, redness, pain at the injection site, firmness, discoloration (not redness or swelling), or itching as reported in their 30-day daily diaries. These side effects were usually mild (easily tolerated) or moderate (uncomfortable) in severity; although, a few subjects experienced severe (disabling) side effects, which included tenderness, bruising, or swelling. Most of these side effects went away on their own within 30 days. Subjects also experienced similar side effects after **repeat injection**.

**Table 1. Side Effects After Treatment<sup>a,b</sup>**

Side Effect	Likelihood of Experiencing Side Effect
	JUVÉDERM® VOLBELLA® XC
Any Side Effect	58 out of 105 people (56%)
Tenderness	51 out of 105 people (50%)
Bruising	44 out of 105 people (43%)
Swelling	43 out of 105 people (42%)
Lumps/Bumps	40 out of 105 people (39%)
Redness	37 out of 105 people (36%)
Pain	36 out of 105 people (35%)
Firmness	36 out of 105 people (35%)
Discoloration	21 out of 105 people (20%)
Itching	13 out of 105 people (13%)
Other	11 out of 105 people (11%)

<sup>a</sup> Occurring in > 5% of subjects.

<sup>b</sup> Based on the 105 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 were reported by study doctors at any time throughout the study. Ten subjects experienced adverse events, and the most common were the same as those reported in the daily diary, such as bruising and swelling. All of these adverse events were mild and went away on their

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own within 14 days.

Occasionally, some subjects experienced adverse events that began more than 30 days after treatment. In the clinical study, 3 subjects had mild swelling that occurred 5 to 10 months after treatment. One subject was prescribed oral antibiotics for the swelling. All of these events went away without any long-term effects.

No subjects experienced adverse events after **repeat injection**.

### **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 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 (lumps/bumps), 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 one 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 within 1 day after injection. Treatment included steroids and antihistamines
- Infection generally occurred during the first month after injection. Treatment included antibiotics, pain killers, antifungals and antibacterial medicines
- Discoloration generally occurred within 3 days after injection. Treatment included antihistamines, **arnica**, **hyaluronidase**, **NSAIDs**, and steroids
- Complications due to blood vessel blockage, for example, vision problems (vision changes), stroke, and **necrosis** generally occurred within 1 week after injection. Treatment included **epinephrine**, **NSAIDs**, **vasodilators**, **hyaluronidase**, hyperbaric oxygen therapy, surgery, and

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warm compress. Outcomes have ranged from completely resolved (for example, vision restored or **necrosis** improved) to ongoing at time of last contact

Other adverse events that were reported included: **abscess**, anxiety, bleeding, cardiac complication (heart problem), deeper wrinkle, depression, discomfort, dizziness, dry skin, extrusion (puffy skin), flu-like symptoms, headache, herpes, increase or decrease in sensation, migration, nausea, scarring, shortness of breath, and tissue hardening

### 9. 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 **under-eye hollows** and 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.

### 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® 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 1.7 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.

### 11. 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 tenderness, bruising, swelling, lumps/bumps, redness, and pain. These side effects usually lasted 1 week 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, heat, and alcoholic beverages. Exposure to any of the above may increase temporary redness,

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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, 61% 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 the majority of subjects. **Repeat injections** are usually needed to maintain your desired result.

## **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® 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. 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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