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
Anemia—an herbal ornament 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)
NASSA—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
Vasoconstrictors—medicines that open blood vessels
VYCOSS® 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.

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 ultrathin 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.
• 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 gapes, 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 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:
• JUVÉDERM® VOLBELLA® XC should only be injected into under-eye hollows by doctors who have completed the necessary training for this treatment area. To find a doctor, visit https://www.juvederm.com/find-a-specialist. Doctors who complete the training will be listed with a symbol.
• Minimize strenuous exercise and exposure to extreme 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 plan to have 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 increase in the chance 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 scarring.
• 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 hollows 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:
• 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
• 90% of subjects were satisfied through 1 year after treatment

(Continued on reverse side.)
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 1

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Likelihood of Experiencing Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Side Effect</td>
<td>58 out of 105 people (56%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>51 out of 105 people (50%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>44 out of 105 people (43%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>43 out of 105 people (42%)</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>40 out of 105 people (39%)</td>
</tr>
<tr>
<td>Redness</td>
<td>37 out of 105 people (36%)</td>
</tr>
<tr>
<td>Pain</td>
<td>36 out of 105 people (35%)</td>
</tr>
<tr>
<td>Firmness</td>
<td>36 out of 105 people (35%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>21 out of 105 people (20%)</td>
</tr>
<tr>
<td>Itching</td>
<td>13 out of 105 people (13%)</td>
</tr>
<tr>
<td>Other</td>
<td>11 out of 105 people (11%)</td>
</tr>
</tbody>
</table>

*Occurring in > 5% of subjects.
*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 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 adverse events went away without any long-term effects.

No subjects experienced adverse events after repeat injection.

What are other possible adverse events? What is the 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 the United States? The most commonly reported adverse events were swelling, redness, bruising, pain, nodules (lumps/bumps), and inflammation.

- Swelling, redness, and pain generally occurred from immediate 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 5 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, skin 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.
- Skin 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 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), deep vein thrombosis, depression, discomfort, dizziness, dry skin, product coming back out, flu-like symptoms, headache, herpes, collection of blood outside of a blood vessel, increase or decrease in sensation, device migration, nausea, necrosis, scarring, shortness of breath, tissue hardening, vision abnormalities, loss/of, correction, unsatisfactory results, varied injuries, rash, blister, overcorrection, drainage, swelling from reactive blood vessels, cyst, acne, swollen lymph nodes, autoimmune disorder exacerbation, combination of any of these side effects, blood vessel occlusion, and skin necrosis.

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 infections or, rarely, reactions to the injection site. Typically, the reported inflammation was responsive to treatment or resolved on its own.

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 pre-treatment 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 of time after each injection 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 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 extreme sun, 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, 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 dropping, 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 within 5 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, you should call your doctor. You may also contact the Allergan Product Surveillance line during normal business hours at 1-877-345-5372 or report the side effects and any other occurrence of any adverse event 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.