Before beginning your treatments, please review this important information.

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

   **Anesthetic**—a substance that reduces sensitivity to pain

   **BDDDE**—a small biodegradable compound added to crosslink the HA in 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 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

   **Lidocaine**—a synthetic compound used as a local anesthetic to decrease pain

   **Pigmentation disorder**—a medical condition that results in changes 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**—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 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

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 BDDDE is added to crosslink the HA in the gel. VYCROSS® technology results in a specialized smooth-gel filler that produces long-lasting results at the treatment site. JUVÉDERM® VOLUMA™ XC is delivered by an injection into the cheek and surrounding area of the mid-face to correct volume and fullness.

3. INDICATION/INTENDED USE
   **What is it for?**
   JUVÉDERM® VOLUMA™ XC is indicated for deep (subcutaneous and/or superficial) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.

   **What does it do?**
   As you age, the cheek area loses its youthful shape. The cheeks flatten out and the skin may begin to sag. JUVÉDERM® VOLUMA™ XC injectable gel is designed to temporarily reverse these signs of aging. It is a gel that is injected into the cheek area to lift the skin. It temporarily adds volume to the cheek area and results in a smoother contour and more youthful appearance to the face. Figure 1 shows the treatment area for JUVÉDERM® VOLUMA™ XC.

   **Figure 1. Treatment Area for JUVÉDERM® VOLUMA™ XC**

   **How is it used?**
   It is injected into the cheek area using a small needle or cannula. It temporarily corrects volume in the cheek area and gives the appearance of a more youthful, smoother skin surface.

4. CONTRAINDICATIONS
   **Are there any reasons why I should not receive JUVÉDERM® VOLUMA™ XC injectable gel?**
   Your doctor will want to review your medical history to determine if you are an appropriate candidate for treatment.
   - You should not use the product if you have severe allergies with a history of severe reactions (anaphylaxis). 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 the 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 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 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 35 years or over 65 years.
   - Tell your doctor which areas of your face you would like to have treated. This product is intended for use in the cheek area, as shown in the highlighted regions in Figure 1, found in Section 3. 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 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.

6. RISKS
   **What are possible side effects?**
   In the clinical study, most side effects were moderate (uncomfortable) in nature, and generally lasted 2 to 4 weeks. The most common side effects include temporary reactions at the treatment site such as tenderness, swelling, bruising, lump/bumps, redness, and itching. 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 scars, or permanent scarring of the skin.

7. BENEFITS
   **What will it accomplish?**
   It will temporarily correct volume in the cheeks and cheek area that has been lost due to aging and will provide a smoother contour and more youthful appearance to the face.

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 photographs to help them evaluate any changes you may have experienced. A topical anesthetic (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 into the cheek, 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.

(Continued on reverse side.)
Do the injections hurt? Injections may cause some discomfort during and after the procedure. In the JUVEDERM® VOLUMA™ XC injectable gel clinical study, immediately after injection subjects rated injection pain, on average, as a 3 on a 11-point scale where 0 is no pain and 10 is worst pain imaginable. JUVEDERM® 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 tenderness, swelling, firmness, and lumps/bumps. These side effects generally lasted 2 to 4 weeks. 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 JUVEDERM® VOLUMA™ XC injectable gel. Within the first 24 hours, you should minimize strenuous exercise and exposure to extreme heat or sun. 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 avoid submersion in water for 24 hours. If you experience severe reactions, such as bruising, swelling, or difficulty breathing, seek medical advice immediately.

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 clinical study, 82% of subjects received a touch-up treatment 1 month after initial treatment in order to achieve the desired result. Does the correction last forever? No. While individual results may vary, in the clinical study, the results lasted up to 2 years in a majority of subjects treated with JUVEDERM® VOLUMA™ XC. After this, repeat injections 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 correct lost facial volume 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, speech impediment, 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.

13. CLINICAL STUDIES How was the product studied? To establish the safety and effectiveness of JUVEDERM® VOLUMA™ XC injectable gel, 270 subjects (80% female and 20% male) were treated in the pivotal trial. The study included patients with all Fitzpatrick Skin Types (lightest to darkest). To achieve subjects’ desired results, a touch-up treatment was allowed 1 month after initial treatment. After 2 years or after correction had been lost, whichever was first, subjects were offered an optional repeat treatment.

The amount of JUVEDERM® VOLUMA™ XC injectable gel used in the clinical study to achieve optimal outcomes ranged from 1.2 mL to 13.9 mL, with a median volume of 6.6 mL. In general, the amount of JUVEDERM® VOLUMA™ XC used for the touch-up and repeat treatment was significantly less than the first treatment. For each patient the volume used was based on volume deficit and treatment goals.

To evaluate the safety of JUVEDERM® 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. To evaluate the effectiveness of the product on restoring fullness to the cheek area, a 6-point scale ranging from 0 to 5 was used.

How was the product studied using cannula? To evaluate treatment with JUVEDERM® VOLUMA™ XC injectable gel using cannula, 60 subjects were treated in one cheek with a needle and the other cheek with cannula. JUVEDERM® VOLUMA™ XC with cannula was not studied in patients with darker skin types ( Fitzpatrick Skin Types V and VI).

The median volume of JUVEDERM® VOLUMA™ XC injectable gel was the same for the needle and cannula sides (median 2.0 mL) used in the clinical study to achieve optimal outcomes.

What did the clinical studies show? In the pivotal clinical study, JUVEDERM® VOLUMA™ XC injectable gel was found to effectively correct cheek shape and fullness.

- 96% of subjects had at least a 1-point improvement in their cheek fullness 8 months after treatment.
- Subjects rated themselves as looking an average of 5 years younger 6 months after their last treatment.
- More than 75% of subjects reported an improvement in their overall satisfaction with their facial appearance 2 years after their last treatment.

The pivotal clinical study showed that JUVEDERM® VOLUMA™ XC injectable gel lasts up to 2 years in the majority of subjects.

In the clinical study using cannula, 93% of subjects had at least a 1-point improvement in their cheek fullness at 1 and 3 months after treatment in the cannula-treated cheek.

14. ADVERSE EFFECTS What side effects were seen in the pivotal clinical study? Most subjects in the clinical study experienced tenderness, swelling, firmness, and/or lumps/bumps at the injection site, as reported on their 30-day daily diary. These side effects were usually moderate in severity, did not require treatment, and generally lasted 2 to 4 weeks. Based on the pivotal clinical study, the likelihood of experiencing side effects after initial treatment with JUVEDERM® VOLUMA™ XC is shown below in Table 1. These events were reported less often after repeat treatment.

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Likelihood of Experiencing Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Side Effect</td>
<td>98 out of 100 people (98%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>92 out of 100 people (92%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>86 out of 100 people (86%)</td>
</tr>
<tr>
<td>Firmness</td>
<td>82 out of 100 people (82%)</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>81 out of 100 people (81%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>78 out of 100 people (78%)</td>
</tr>
<tr>
<td>Pain</td>
<td>66 out of 100 people (66%)</td>
</tr>
<tr>
<td>Redness</td>
<td>66 out of 100 people (66%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>41 out of 100 people (41%)</td>
</tr>
<tr>
<td>Itching</td>
<td>39 out of 100 people (39%)</td>
</tr>
</tbody>
</table>

* Occurring in > 5% of subjects

Based on 265 subjects who provided information about side effects after initial treatment.

What adverse events were seen in the clinical study using cannula? Most subjects in the clinical study experienced tenderness, firmness, swelling, and/or lumps/bumps at the injection site, as reported on their 30-day daily diary. These side effects were usually mild or moderate in severity, did not require treatment, and generally lasted 2 weeks. Based on this clinical study, the likelihood of experiencing side effects after treatment using a cannula with JUVEDERM® VOLUMA™ XC is shown below in Table 2.

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Likelihood of Experiencing Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Side Effect</td>
<td>60 out of 60 people (100%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>55 out of 60 people (92%)</td>
</tr>
<tr>
<td>Firmness</td>
<td>50 out of 60 people (83%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>49 out of 60 people (82%)</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>42 out of 60 people (70%)</td>
</tr>
<tr>
<td>Pain</td>
<td>40 out of 60 people (67%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>36 out of 60 people (60%)</td>
</tr>
<tr>
<td>Redness</td>
<td>33 out of 60 people (55%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>22 out of 60 people (37%)</td>
</tr>
<tr>
<td>Itching</td>
<td>11 out of 60 people (18%)</td>
</tr>
</tbody>
</table>

Based on 60 subjects who provided information about side effects after initial treatment with cannula.

What adverse events were seen in the pivotal clinical study? Adverse events (any side effects to JUVEDERM® VOLUMA™ XC that lasted longer than the 30-day daily diary, or side effects that occurred after 30 days) were reported over the course of the study. The most common adverse events were the same as those reported as side effects in the daily diary, such as lumps/bumps, firmness, swelling, and pain. Adverse events were seen more frequently in subjects who received a large volume of product and subjects who were older. Rarely, adverse events occurred weeks to months after the injection procedure.

What adverse events were seen in the clinical study using cannula? Among the 60 subjects treated with JUVEDERM® VOLUMA™ XC using a cannula, 2 subjects experienced one or more related adverse events (lumps and bumps on the needleinkle in one subject and plaque [dry, flaky, rough skin] on both the needle and cannula in another subject).

15. ADDITIONAL INFORMATION What if I experience a problem? If you believe that you have experienced a serious problem related to JUVEDERM® 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.

What should I do if I have additional questions? For further questions and information, please call Allergan at 1-800-766-0171.