Tell your doctor which areas of your face you would like to have treated. This will help avoid unsatisfactory results and complications.

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.

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.

What did the clinical study show?

Subjects reported:

• Overall aesthetic improvement was seen in 93% of subjects at 3 months after treatment
• 62% of subjects had at least a 1-point improvement in lip fullness 1 year after treatment
• 44% of subjects had at least a 1-point improvement in lip fullness 2 years after treatment
• 56% of subjects had at least a 1-point improvement in the appearance of lines around the mouth through 1 year after treatment
• 59% of subjects at 1 year after treatment

It was found that JUVÉDERM® VOLBELLA™ XC lasts through 1 year in the majority of subjects.

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

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.

### Table 1. Side Effects After 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>97 out of 100 people (97%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>93 out of 100 people (93%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>90 out of 100 people (90%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>89 out of 100 people (89%)</td>
</tr>
<tr>
<td>Firmness</td>
<td>89 out of 100 people (89%)</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>88 out of 100 people (88%)</td>
</tr>
<tr>
<td>Redness</td>
<td>83 out of 100 people (83%)</td>
</tr>
<tr>
<td>Pain</td>
<td>81 out of 100 people (81%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>42 out of 100 people (42%)</td>
</tr>
<tr>
<td>Itching</td>
<td>31 out of 100 people (31%)</td>
</tr>
<tr>
<td>Dryness</td>
<td>5 out of 100 people (5%)</td>
</tr>
</tbody>
</table>

*Occurring in > 5% of subjects.

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).

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?

Based on the 168 subjects treated with 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.