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 extended 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 established.

• 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 22 years or over 80 years.

• Tell your doctor if the area of your face you would like to have treated has had a previous skin condition or surgery. 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 excessive scarring (thick, hard scars). The safety of JUVÉDERM® VOLUMA™ 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® VOLUMA™ XC in patients with a history of pigmentation disorders has not been studied. Use in these patients may result in changes in pigmentation.

6. RISKS

What are possible side effects?

In the clinical study, most side effects were mild (easily tolerated) in nature, and generally resolved in 2 to 4 weeks. The most common side effects include temporary swelling, bruising, redness, itching, and discoloration. These side effects are consistent with other facial-injection procedures. See Section 14 for additional information on side effects to the chin.

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 of using this product is unintentional injection into a blood vessel. The risks 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.

What side effects have been reported through voluntary postmarket surveillance? JUVÉDERM® VOLUMA™ XC use in and outside of the United States?

The most commonly reported adverse events were swelling, redness, bruising, pain, nodules, and inflammation.

• Swelling, redness, and pain generally occurred from immediately to 2 months after injection. The treatment prescribed included NSAIDs, anti-inflammatories, 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, anti-inflammatories, antibiotics, steroids, arnica, and hyaluronidase. In most cases, it went away within a few days to 6 weeks.

• Nodules generally occurred from immediately to 2 months after injection. Treatment included antibiotics, steroids, and hyaluronidase. In most cases, nodules went away within 1 month.

• Inflammation generally occurred from the day of treatment to 4 months after injection. Treatment included antibiotics, steroids, and needle aspiration. Resolution of symptoms has not been reported within 4 days.

Additionally, there have been reports of allergic reaction, infection, skin discoloration, and blood vessel blockage.

• Allergic reaction generally occurred from immediately to 1 day after injection. Treatment included steroids and anti-inflammatories.

• Infection generally occurred from immediately to 1 month after injection. Treatment included antibiotics, pain killers, antifungals, and antibacterial medicines.

• Skin discoloration generally occurred from immediately to 1 month after injection. Treatment included anti-inflammatories, arnica, hyaluronidase, NSAIDs, and steroids.

• Blood vessel blockage generally occurred from immediately to 1 week 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.

(Continued on reverse side.)
13. CLINICAL STUDIES

How was the product studied?

To establish the safety and effectiveness of JUVÉDERM® VOLUMA™ XC injectable gel for augmentation, 192 subjects (89% female and 11% male) were treated. To achieve subjects’ desired results, a touch-up treatment was allowed 1 month after initial treatment. After 1 year, subjects were offered an optional repeat treatment.

The amount of JUVÉDERM® VOLUMA™ XC injectable gel used in the clinical study to achieve optimal outcomes ranged from 0.7 ml to 4.0 ml, with a median volume of 2.4 ml. In general, the amount of JUVÉDERM® VOLUMA™ XC used for the touch-up and repeat treatments was significantly less than the first treatment. For each patient the volume used was based on the desired deficit and treatment goals.

To evaluate the safety of JUVÉDERM® 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 effectiveness, the product for chin augmentation, a 5-point scale ranging from 0 to 4 was used.

What did the clinical study show?

JUVÉDERM® VOLUMA™ XC injectable gel was found to effectively augment the chin.

- Based on 2D photo assessment by the doctor using the 5-point phonomeric
Allergan Chin Retrusion Scale (ACRS), 56% of subjects had at least a 1-point improvement in their chin profile 6 months after treatment.
- Based on in-person live assessment by the doctor using the ACRS, 92% of subjects had at least a 1-point improvement in their chin profile 6 months after treatment.
- The following subjects did not meet the primary study endpoint of 50% of subjects who had at least a 1-point improvement in their chin profile 6 months after treatment based on the 2D photo assessment: those aged 51.5 years and older (46% of treated subjects showed improvement), those with darker skin (29%), and those with malar facies. However, satisfaction was still high among these subjects.
- More than 90% of subjects reported an improvement in their overall satisfaction with how their chin looked at 1 year after treatment.
- Most of the subjects (>85%) reported satisfaction with how their chin suits their facial features and the treatment goals.

The clinical study showed that the JUVÉDERM® VOLUMA™ XC injectable gel treatment in the chin lasts up to 1 year in the majority of subjects.

14. ADVERSE EFFECTS

What side effects were seen in the clinical study?

Most subjects in the clinical study experienced tenderness and/or firmness at the injection site, as reported in their 30-day daily diary. These side effects were usually mild in severity, did not require treatment, and generally resolved in 1 week. Side effects lasting 15 to 30 days were experienced by 35% of subjects, and severe side effects were experienced by 12% of subjects. Based on the information from the study, the incidences of side effects after initial treatment with JUVÉDERM® VOLUMA™ XC in the chin area 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>92% of people (92%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>82% of people (82%)</td>
</tr>
<tr>
<td>Firmness</td>
<td>75% of people (75%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>69% of people (69%)</td>
</tr>
<tr>
<td>Pain</td>
<td>63% of people (63%)</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>60% of people (60%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>59% of people (59%)</td>
</tr>
<tr>
<td>Redness</td>
<td>49% of people (49%)</td>
</tr>
<tr>
<td>Icing</td>
<td>28% of people (28%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>15% of people (15%)</td>
</tr>
</tbody>
</table>

Occurring in >5% of subjects.

What adverse events were seen in the clinical study?

Adverse events (any side effects to JUVÉDERM® VOLUMA™ XC for chin augmentation reported by the doctors) were reported over the course of the study. The most common side effects associated with the JUVÉDERM® VOLUMA™ XC treatment were injection-site related. Injection-site related side effects included:

- Induration
- Discoloration
- Bruising
- Redness
- Icing
- Lumps/Bumps
- Pain
- Firmness
- Swelling

The most common injection-site related side effects were induration and discoloration. These side effects were usually mild in severity and did not require treatment. None of these injection-site related side effects were new or different from the findings in previous JUVÉDERM® VOLUMA™ XC and JUVÉDERM® VOLUMA™ XC injectable gel studies.

A total of 11 subjects experienced 14 serious adverse events (SAEs) after treatment with JUVÉDERM® VOLUMA™ XC for chin augmentation. Of the 14 SAEs, two (injection-site inflammation and injection-site cellulitis, which is a type of skin infection) were treated with repeat injections treatment. The events of swelling resolved within 3 days with medication.

15. ADDITIONAL INFORMATION

What if I experience a problem?

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