Before beginning your treatments, please review this important information.

Glossary of terms
(Note that terms in the glossary are bolded throughout this document.)

- **Abscess**—a swollen lump filled with pus
- **Anaphylaxis**—severe allergic reaction
- **Anesthetic**—a substance that reduces sensitivity to pain
- **Anticoagulants**—a substance that prevents or reduces blood clots
- **Arnica**—an herbal ointment that is commonly used to treat pain, bruising, and swelling
- **Bovine-based collagen**—a dermal filler created from cowhides
- **Complimentary**—free, at no cost
- **Cushioning agent**—absorbs shock
- **Duration**—length of time
- **Epinephrine**—a medication used in emergencies to treat serious allergic reactions
- **Expressed a preference**—subjects liked better
- **Gram-positive bacterial proteins**—remnants of protein from the bacteria that produce the hyaluronic acid used in JUVÉDERM® Ultra XC
- **Hyaluronidase**—an enzyme that breaks down hyaluronic acid
- **Hypertrophic scarring**—a thick, hard scar that grows over the injured area
- **Inflammatory reaction**—a localized response to injury, typically including pain, heat, redness, and swelling
- **Injection-site responses**—side effects from treatment
- **Keloid formation**—a thick, hard scar that grows outside the injured area
- **Nasolabial folds (NLFs)**—the lines or wrinkles that run from the corners of the nose downward toward the corners of the mouth
- **Necrosis**—death of living tissue (skin)
- **NSAIDs**—nonsteroidal anti-inflammatory drug, such as aspirin or ibuprofen
- **Optimal**—the best possible outcome
- **Pigmentation disorders**—a lightening or darkening of an area of the skin
- **Repeat treatment or 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 injection**—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 injection may be necessary to achieve the desired result
- **Vasodilators**—medicines that open blood vessels

What is it?
JUVÉDERM® Ultra XC injectable gel is a colorless hyaluronic acid gel that contains a small quantity of local anesthetic (lidocaine) and is injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth. Hyaluronic acid is a naturally occurring sugar found in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding in water, and to act as a cushioning agent. The role of lidocaine is to reduce the pain associated with injections into the skin.

What does it do?
JUVÉDERM® Ultra XC temporarily adds volume to facial tissue and restores a smoother appearance to the face. The lidocaine in the gel improves the comfort of the injection.

How is it used?
JUVÉDERM® Ultra XC is injected into areas of facial tissue where moderate to severe facial wrinkles and folds occur. It temporarily adds volume to the skin and may give the appearance of a smoother surface.

What will it accomplish?
JUVÉDERM® Ultra XC injectable gel will help to smooth moderate to severe facial wrinkles and folds. Most patients need 1 treatment to achieve optimal wrinkle smoothing, and the results last about 9 months to 1 year.

What are possible side effects?
Most side effects are mild or moderate in nature, and their duration is short lasting (7 days or less). The most common side effects include, but are not limited to, temporary injection-site responses such as: redness, pain/tenderness, firmness, swelling, lumps/bumps, bruising, itching, and discoloration.

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 scabs, or permanent scarring of the skin.

Are there any reasons why I should not receive JUVÉDERM® Ultra XC?
Your physician will ask about your medical history to determine if you are an appropriate candidate for treatment. The product should not be used in patients who have:

- Severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies

- A history of allergies to lidocaine or Gram-positive bacterial proteins

What should my physician warn me about?
The safety and effectiveness for the treatment of areas other than facial wrinkles and folds and lips have not been established in controlled clinical studies. For more information on treating the lips, refer to the JUVÉDERM® Ultra XC for Lip Augmentation Patient Labeling document.

What precautions should my physician advise me about?
The following are important treatment considerations for you to discuss with your physician and understand in order to help avoid unsatisfactory results and complications.

- Patients who are using substances that can prolong bleeding, such as aspirin or ibuprofen, as well as any injection, may experience increased bruising or bleeding at injection site. You should inform your physician before treatment if you are using these types of substances
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with JUVÉDERM® Ultra XC, there is a possible risk of an inflammatory reaction at the treatment site
- JUVÉDERM® Ultra XC injectable gel should be used with caution in patients on immunosuppressive therapy, or therapy used to decrease the body’s immune response, as there may be an increased risk of infection
- The safety for use during pregnancy, in breast-feeding females, or in patients under 18 years has not been established
- The safety in patients with a history of excessive scarring (eg, hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied

What did the clinical study show?
In the primary US clinical study to establish safety and effectiveness, 146 subjects were followed for 24 weeks after injection with JUVÉDERM® Ultra (without lidocaine) in 1 nasolabial fold (NLF) and ZYPLAST® dermal filler (bovine-based collagen) in the other. The percentage of subjects who reported common injection-site responses are presented in the table below.

### Table 1. Injection-Site Side Effects (Nasolabial Folds) N = 146

<table>
<thead>
<tr>
<th>Injection-Site Responses</th>
<th>JUVÉDERM® Ultra</th>
<th>ZYPLAST®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redness</td>
<td>136</td>
<td>130</td>
</tr>
<tr>
<td>93%</td>
<td>98%</td>
<td>89%</td>
</tr>
<tr>
<td>Pain/Tenderness</td>
<td>131</td>
<td>128</td>
</tr>
<tr>
<td>90%</td>
<td>90%</td>
<td>88%</td>
</tr>
<tr>
<td>Firmness</td>
<td>129</td>
<td>127</td>
</tr>
<tr>
<td>88%</td>
<td>87%</td>
<td>87%</td>
</tr>
<tr>
<td>Swelling</td>
<td>125</td>
<td>122</td>
</tr>
<tr>
<td>86%</td>
<td>84%</td>
<td>84%</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>115</td>
<td>122</td>
</tr>
<tr>
<td>79%</td>
<td>84%</td>
<td>84%</td>
</tr>
<tr>
<td>Bruising</td>
<td>86</td>
<td>80</td>
</tr>
<tr>
<td>59%</td>
<td>55%</td>
<td>55%</td>
</tr>
<tr>
<td>Itching</td>
<td>52</td>
<td>53</td>
</tr>
<tr>
<td>36%</td>
<td>36%</td>
<td>36%</td>
</tr>
<tr>
<td>Discoloration</td>
<td>48</td>
<td>49</td>
</tr>
<tr>
<td>33%</td>
<td>34%</td>
<td>34%</td>
</tr>
</tbody>
</table>

* Occurring in > 5% of subjects.

* Number of subject NLFs with each specific injection-site response.

Injection-site responses were similar in duration and frequency for the JUVÉDERM® Ultra injectable gel and ZYPLAST® treated sides, were usually mild or moderate in severity, did not require intervention, and lasted 7 days or less.

JUVÉDERM® Ultra was found to provide a more persistent wrinkle correction than ZYPLAST® dermal filler over the 24-week course of the study. The percentage of subjects who maintained improvement with JUVÉDERM® Ultra at 24 weeks was 88% compared to 36% with ZYPLAST®. At the conclusion of the study, 129 (88%) of the 146 subjects expressed a preference for JUVÉDERM® Ultra injectable gel, while only 8 (5%) expressed a preference for ZYPLAST®, and 9 (6%) had no preference.

[Figure 1. Subject Preference]

(Continued on reverse side.)
What did the clinical study show? (continued)

Subjects who completed the 24-week study were invited to return for a complimentary repeat treatment. Subjects returned at their (or their physician’s) convenience. Of the 146 subjects, 116 (79%) returned for repeat treatment, on average at 9 months after their last injection. Forty-eight (48) subjects returned more than 36 weeks (9 months) after their last injection: the percentage of those subjects who had maintained improvement with JUVÉDERM® Ultra was 75%.

At multiple time points in the clinical study, subjects’ nasolabial folds were rated on a scale from 0 to 4. Using this 5-point wrinkle assessment scale, the mean improvement since baseline was 1.9 at 2 weeks, 1.4 at 24 weeks, and 1.1 beyond 36 weeks after treatment.

Table 2. Wrinkle Assessment Scale (Nasolabial Folds)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
</tr>
<tr>
<td>3</td>
<td>Severe</td>
</tr>
<tr>
<td>4</td>
<td>Extreme</td>
</tr>
</tbody>
</table>

In another clinical study comparing JUVÉDERM® Ultra with and without lidocaine, 36 subjects received the product with lidocaine in 1 nasolabial fold and the product without lidocaine in the other. Subjects rated the level of pain during each injection. Pain was significantly less on the side that received JUVÉDERM® Ultra XC, and in comparing the 2 injections, 34 subjects (94%) found the lidocaine formulation to be less painful.

What side effects have been reported through voluntary postmarket surveillance of JUVÉDERM® Ultra and JUVÉDERM® Ultra Plus (with or without lidocaine) use in and outside of the United States? The most commonly reported adverse events were swelling, redness, bruising, and pain.

- Swelling, redness, and pain generally occurred from 2 to 6 months after injection. Treatment prescribed included NSAIDs, antihistamines, antibiotics, steroids, 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, hyaluronidase. In most cases, it went away within a few days to 6 weeks

Additionally, there have been reports of nodules, infection, inflammation, allergic reaction, and blood vessel blockage.

- Nodules generally occurred from immediately to 2 months after injection. Treatment included NSAIDs, antibiotics, steroids, hyaluronidase. In most cases, nodules went away within 1 month
- Infection generally occurred from immediately to 1 month after injection. Treatment included antibiotics, pain killers, antifungals, and antibacterial medicines
- Allergic reaction generally occurred from immediately to 1 day after injection. Treatment included antihistamines and steroids
- Inflammation generally occurred from the day of treatment to 4 months after injection. Treatment included antibiotics, steroids, and needle aspiration. Resolution of symptoms has been reported within 4 days

Blood vessel blockage generally occurred from immediately to 1 week after injection. Treatment included anticoagulants, epinephrine, NSAIDs, vasodilators, hyaluronidase, surgery, and warm compress. Outcomes have ranged from completely resolved to ongoing at time of last contact.

Other adverse events that were reported included: blister, skin rash, bleeding at the injection site, necrosis at the injection site, abscess at the injection site, increase or decrease in sensation, skin discoloration, device migration, dry skin, headache, flu-like symptoms, vision abnormalities, herpetic ulceration, dizziness, nausea, depression, lack or loss of correction, unsatisfactory result, overcorrection, varied injuries, discomfort, drainage, product coming back out, acne, shortness of breath, passing out, cardiac complication, deeper wrinkling, collection of blood outside of a blood vessel, swelling from reactive blood vessels, spider vein, tissue hardening, and cyst.

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 illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own. Other adverse events that were reported included: blister, skin rash, bleeding at the injection site, necrosis at the injection site, abscess at the injection site, increase or decrease in sensation, skin discoloration, device migration, dry skin, headache, flu-like symptoms, vision abnormalities, herpetic ulceration, dizziness, nausea, depression, lack or loss of correction, unsatisfactory result, overcorrection, varied injuries, discomfort, drainage, product coming back out, acne, shortness of breath, passing out, cardiac complication, deeper wrinkling, collection of blood outside of a blood vessel, swelling from reactive blood vessels, spider vein, tissue hardening, and cyst.

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What should I expect following the procedure? Your physician will tell you what to expect following treatment with JUVÉDERM® Ultra XC. Within the first 24 hours, you should avoid strenuous exercise, extensive sun or heat exposure, and alcoholic beverages. Exposure to any of the above may cause temporary redness, swelling, and/or itching at the injection sites. If there is swelling, you may need to place an ice pack over the swollen area. You should ask your physician when makeup may be applied after your treatment.

Does the correction last forever? No. Correction is temporary; therefore, touch-up injections as well as repeat injections are usually needed to maintain optimal correction. Less material (about half the amount) is usually needed for repeat injections.

What other treatments are available to me? There are a variety of dermal fillers available in the United States that may be used for treatment. Aside from these, additional options for the correction of lines and wrinkles do exist, including facial creams, neurotoxins, chemical peels, and laser skin surface treatments. You may discuss these treatments with your physician.

When should I notify my physician? 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, or
4. Unusual pain during or shortly after treatment

Be sure to also call your doctor if you have:

1. Any 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 Support line at 1-877-345-5372.

For further questions and information, please call Allergan at 1-800-766-0171.