About JUVÉDERM® Ultra

Before beginning your treatments, please review this important information.

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

**Anaphylaxis**—severe allergic reaction

**Bovine-based collagen**—a dermal filler created from cowhides

**Complimentary**—free, at no cost

**Cushioning agent**—absorbs shock

**Duration**—length of time

**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

**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

**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

**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

What is it?

JUVÉDERM® Ultra injectable gel is a colorless hyaluronic acid gel that 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.

What does it do?

JUVÉDERM® Ultra injectable gel temporarily adds volume to facial tissue and restores a smoother appearance to the face.

How is it used?

JUVÉDERM® Ultra injectable gel is injected into areas of facial tissue where moderate to severe facial wrinkles and folds occur. JUVÉDERM® Ultra injectable gel temporarily adds volume to the skin and may give the appearance of a smoother surface.

What will it accomplish?

JUVÉDERM® Ultra injectable gel will help to smooth moderate to severe facial wrinkles and folds. Most patients need one 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 injectable gel?

Your physician will ask about your medical history to determine if you are an appropriate candidate for treatment. JUVÉDERM® Ultra injectable gel should not be used in patients who have:

- Severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies
- Patients with a history of allergies to Gram-positive bacterial proteins

What 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 with any injection, may experience increased bruising or bleeding at the 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 injectable gel, there is a possible risk of an inflammatory reaction at the treatment site
- JUVÉDERM® Ultra 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 of JUVÉDERM® Ultra injectable gel for use during pregnancy, in breastfeeding females, or in patients under 18 years has not been established
- The safety of JUVÉDERM® Ultra injectable gel in patients with a history of excessive scarring (e.g., hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied

What should my physician warn me about?

The safety and effectiveness of JUVÉDERM® Ultra injectable gel for the treatment of areas other than facial wrinkles and folds (such as lips) have not been established in controlled clinical studies.

What did the clinical study show?

In a US clinical study, 146 subjects were followed for 24 weeks after injection with JUVÉDERM® Ultra injectable gel in one nasolabial fold (NLF) and ZYPLAST® dermal filler (bovine-based collagen) in the other. The percentage of subjects who reported common injection site responses is presented in the table below.

<table>
<thead>
<tr>
<th>Injection Site Responses* N = 146</th>
<th>JUVÉDERM® Ultra</th>
<th>ZYPLAST®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redness</td>
<td>n**</td>
<td>%</td>
</tr>
<tr>
<td>Pain/Tenderness</td>
<td>136</td>
<td>93%</td>
</tr>
<tr>
<td>Firmness</td>
<td>131</td>
<td>90%</td>
</tr>
<tr>
<td>Swelling</td>
<td>129</td>
<td>88%</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>125</td>
<td>86%</td>
</tr>
<tr>
<td>Bruising</td>
<td>115</td>
<td>79%</td>
</tr>
<tr>
<td>Itching</td>
<td>86</td>
<td>59%</td>
</tr>
<tr>
<td>Discoloration</td>
<td>52</td>
<td>36%</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® dermal filler treated sides, were
What did the clinical study show? (continued)

Usually mild or moderate in severity, did not require intervention, and lasted 7 days or less.

JUVÉDERM® Ultra injectable gel 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 injectable gel at 24 weeks was 88% compared to 36% with ZYPLAST® dermal filler. 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® dermal filler, and 9 (6%) had no preference.

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, rather than at a prescribed time point. 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:

- 1.4 at 24 weeks, and
- 1.1 beyond 36 weeks after treatment.

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A subset of these subjects enrolled in a second study that followed subjects for 24 to 48 weeks after repeat treatment. Twenty-four (24) subjects were enrolled in the study. Twenty-three (23) were evaluated at 24 weeks (6 months) after repeat treatment with 87% maintaining improvement. Nine (9) subjects returned for evaluation 48 weeks (1 year) after repeat treatment: the percentage of those subjects who had maintained improvement with JUVÉDERM® Ultra injectable gel was 78%.

The mean improvement since baseline at different time points after repeat treatment was 1.4 at 24 weeks and 1.3 at 48 weeks after repeat treatment.