About JUVÉDERM® Ultra

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.)

Abscess—a swollen lump filled with pus

Anaphylaxis—severe allergic reaction

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

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

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 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 (eg, **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.

Injection-Site Responses[a] N = 146

	JUVÉDERM® Ultra		ZYPLAST®	
Injection-Site Responses	**n[b]**	**%**	**n[b]**	**%**
Redness	136	93%	130	89%
Pain/Tenderness	131	90%	128	88%
Firmness	129	88%	127	87%
Swelling	125	86%	122	84%
Lumps/Bumps	115	79%	122	84%
Bruising	86	59%	80	55%
Itching	52	36%	53	36%
Discoloration	48	33%	49	34%

[a]Occurring in > 5% of subjects.

[b]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 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.

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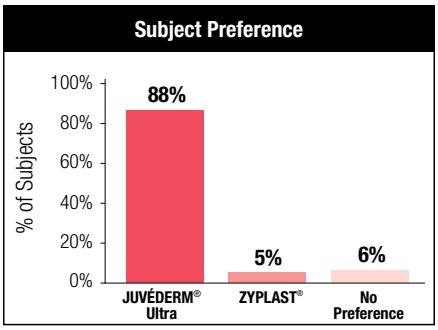
What did the clinical study show? (continued)

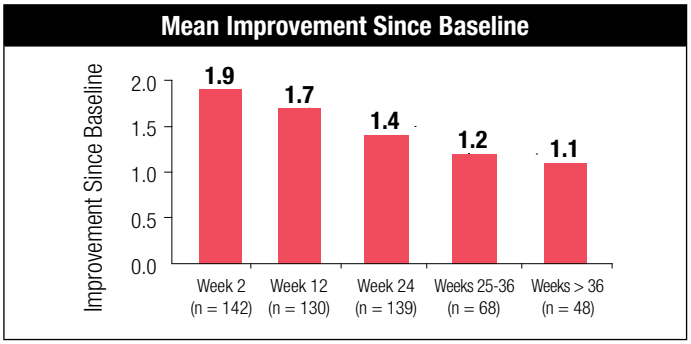
The percentage of subjects who maintained improvement with JUVÉDERM® Ultra injectable gel at 24 weeks was 88% compared to 36% with ZYPLAST® dermal filler. At the conclusion of the study, 129 (88%) of the 146 subjects **expressed a preference** for JUVÉDERM® Ultra injectable gel, while only 8 (5%) **expressed 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: the percentage of those subjects who had maintained improvement with JUVÉDERM® Ultra injectable gel was 75%.

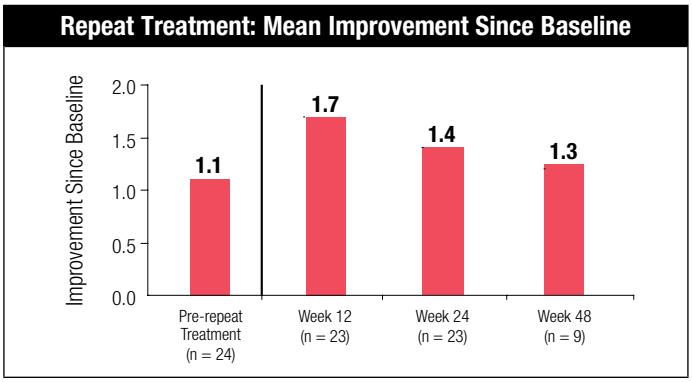
0	None
1	Mild
2	Moderate
3	Severe
4	Extreme

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.



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**.



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 immediately to 2 months after injection. The treatment prescribed included **NSAIDs**, antihistamines, 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**, antihistamines, antibiotics, steroids, **arnica**, and **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, and **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
- 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
- Allergic reaction generally occurred from immediately to 1 day after injection. Treatment included steroids and antihistamines
- 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, herpes, anxiety, scarring, 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 wrinkle, spider vein, collection of blood outside of a blood vessel, swelling from reactive blood vessels, tissue hardening, and severe life-threatening allergic reaction.

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.

Do the injections hurt?

Injections may cause some discomfort during and after the injection. JUVÉDERM® Ultra injectable gel is injected directly into the skin using a fine needle to reduce injection discomfort. Physicians may choose to numb (anesthetize) the treatment area to further minimize discomfort.

What should I expect following the procedure?

Your physician will tell you what to expect following treatment with JUVÉDERM® Ultra injectable gel. 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?

Other treatments for dermal soft-tissue augmentation include **bovine-based collagen** and other hyaluronic acid–based dermal fillers. Aside from these treatments, additional options for the correction of lines and wrinkles do exist, including facial creams, neurotoxins, chemical peels, and laser skin surface treatments, and may be discussed 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 headaches, 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 Surveillance line during normal business hours at 1-877-345-5372 to report any side effects.

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

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05/2023 022769 20079121