About JUVÉDERM™ Ultra Plus

Juvéderm™ ULTRA PLUS

Before beginning your treatments, please review this important information.

What is it?

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

How is it used?

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

What will it accomplish?

JUVÉDERM™ Ultra Plus 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 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 reactions 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.

Are there any reasons why I should not receive JUVÉDERM™ Ultra Plus injectable gel?

Your physician will ask about your medical history to determine if you are an appropriate candidate for treatment. JUVÉDERM™ Ultra Plus 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 Plus injectable gel, there is a possible risk of an inflammatory reaction at the treatment site
- JUVÉDERM™ Ultra Plus 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 Plus injectable gel for use during pregnancy, in breastfeeding females, or in patients under 18 years has not been established
- The safety of JUVÉDERM™ Ultra Plus 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 Plus 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, 144 subjects were followed for 24 weeks after injection with JUVÉDERM™ Ultra Plus 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* N = 144				
	JUVÉDERM™ Ultra Plus		ZYPLAST®	
Injection-Site Responses	**n****	**%**	**n****	**%**
Redness	129	90%	128	89%
Pain/Tenderness	129	90%	123	85%
Firmness	127	88%	122	85%
Swelling	124	86%	121	84%
Lumps/Bumps	120	83%	113	78%
Bruising	87	60%	69	48%
Itching	49	34%	51	35%
Discoloration	49	34%	43	30%

*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 Plus 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 Plus injectable gel was found to provide a more persistent wrinkle correction than ZYPLAST® dermal filler over the 24-week course of

(Continued on other side)

See other side for Consent Form

Juvéderm™ ULTRA PLUS

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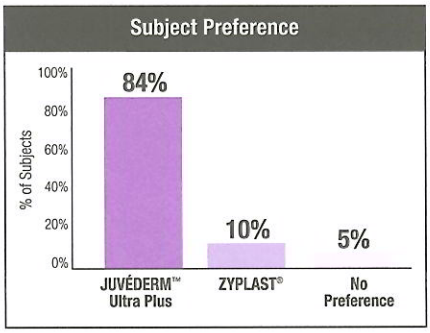
Notes:_____

What did the clinical study show? (Continued from front side.)

the study. The percentage of subjects who maintained improvement with JUVÉDERM™ Ultra Plus injectable gel at 24 weeks was 90% compared to 40% with ZYPLAST® dermal filler. At the conclusion of the study, 123 (84%) of the 146 subjects expressed a preference for JUVÉDERM™ Ultra Plus injectable gel, while only 15 (10%) expressed a preference for ZYPLAST® dermal filler, and 8 (5%) had no preference.

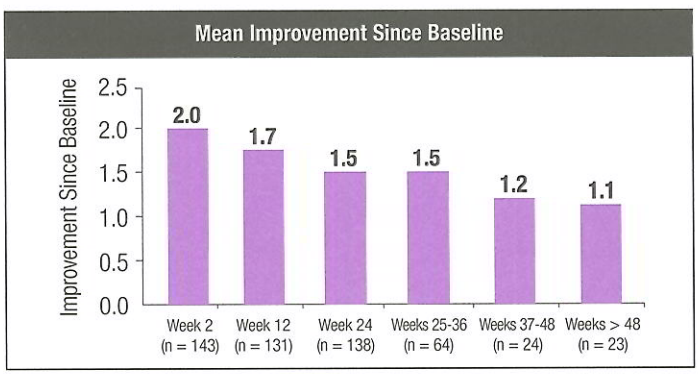


Subjects who completed the 24-week study were invited to return for a complimentary repeat treatment. Subjects returned at their (or their physician's) convenience, rather than at a prescribed time point. Of the 146 subjects, 111 (76%) returned for repeat treatment, on average at 9 months after their last injection. Forty-seven (47) subjects returned more than 36 weeks (9 months) after their last injection: the percentage of those subjects who had maintained improvement with JUVÉDERM™ Ultra Plus injectable gel was 81%. Of the twenty-three (23) subjects who returned more than 48 weeks (1 year) after their last injection, 78% had maintained improvement.

At multiple time points in the clinical study, subjects' nasolabial folds were rated on a scale from 0 to 4:

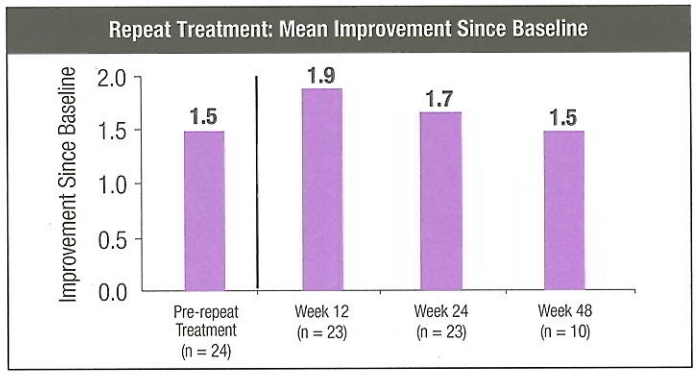
0	None
1	Mild
2	Moderate
3	Severe
4	Extreme

Using this 5-point wrinkle assessment scale, the mean improvement since baseline was 2.0 at 2 weeks, 1.5 at 24 weeks, and 1.1 beyond 48 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 91% maintaining improvement. Ten (10) subjects returned for evaluation 48 weeks (1 year) after repeat treatment: the percentage of those subjects who had maintained improvement with JUVÉDERM™ Ultra Plus injectable gel was 90%.

The mean improvement since baseline at different time points after repeat treatment was 1.7 at 24 weeks, and 1.5 at 48 weeks after repeat treatment.



Do the injections hurt?

Injections may cause some discomfort during and after the injection. JUVÉDERM™ Ultra Plus 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 Plus 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, BOTOX® Cosmetic (Botulinum Toxin Type A), chemical peels, and laser skin surface treatments, and may be discussed with your physician.

When should I notify my physician?

Be sure to report any redness and/or visible swelling that lasts for more than a few days, or any other symptoms that cause you concern, to your physician and/or contact the Allergan Product Support line at 1-877-345-5372.

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

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Consent

(Note: Sign, remove, and file in patient record.)

I have read the information titled "About JUVÉDERM™ Ultra Plus" in its entirety and have discussed the risks and benefits of dermal filler treatment with my physician and his/her representative. I understand the information provided. I agree to my being treated with JUVÉDERM™ Ultra Plus.

Patient's Signature _____ Date _____

I have discussed the risks and benefits of dermal filler treatment with this patient, have answered his/her questions, and find him/her an appropriate candidate for treatment with JUVÉDERM™ Ultra Plus.

Signature of Physician or Physician's Representative _____ Date _____