

What did the clinical study show?

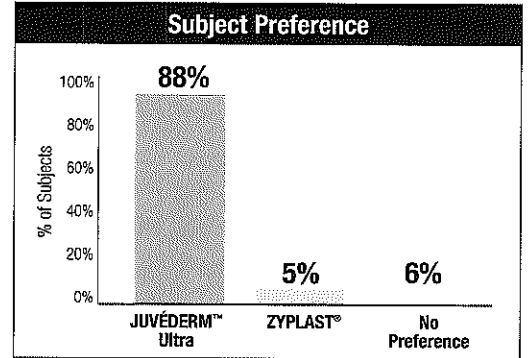
In a US clinical study, 146 subjects were followed for 24 weeks after injection with JUVÉDERM™ Ultra injectable gel in one nasolabial fold and ZYPLAST® dermal filler (bovine-based collagen) in the other. The percentage of subjects who reported common injection-site responses are presented in the table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

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.

Injection-Site Responses* N = 146				
	JUVÉDERM™ Ultra		ZYPLAST®	
Injection-Site Responses	n**	%	n**	%
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%

*Occurring in > 5% of subjects.
 ** Number of subject NLFs with each specific injection-site response.

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.



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.

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.

Consent

I have read the information titled "About JUVÉDERM™ Ultra" 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.

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.

Signature of Physician or Physician's Representative _____ Date _____

Before beginning your treatments, please review this important information.

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 six months.

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 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.

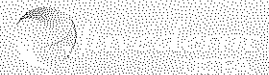
- Patients who are using substances that can prolong bleeding, such as aspirin or ibuprofen, as with any injection, may experience increased bruising or bleeding at injection site. You should inform your physician before treatment if you are using these types of substances
- If laser treatment, chemical 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.

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Notes: _____

