

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.

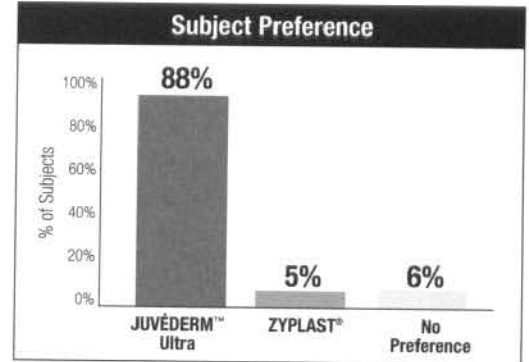
What other treatments are available to me?

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.



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Consent

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

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 _____