

Juvéderm® 30HV
Patient Information Labeling

What is it? Juvéderm 30HV 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 30HV temporarily adds volume to facial tissue and restores a smoother appearance to the face.

How is it used? Juvéderm 30HV is injected into areas of facial tissue where moderate to severe facial wrinkles and folds occur. Juvéderm 30HV temporarily adds volume to the skin and may give the appearance of a smoother surface.

What will it accomplish? Juvéderm 30HV 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 30HV?

Your physician will ask about your medical history to determine if you are an appropriate candidate for treatment. Juvéderm 30HV 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 30HV, there is a possible risk of an inflammatory reaction at the treatment site.
- Juvéderm 30HV 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 30HV for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- The safety of Juvéderm 30HV 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 30HV 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 U.S. clinical study 144 subjects were followed for 24 weeks after injection with Juvéderm 30HV in one nasolabial fold and Zyplast® (bovine-based collagen) in the other. The percentage of subjects who reported common injection site responses are presented in the table below.

Injection Site Responses*
N = 144

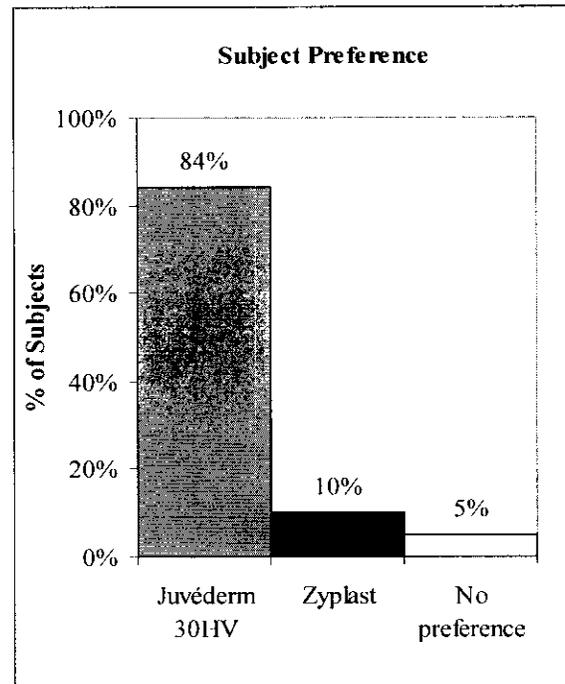
| Injection Site Responses | Juvéderm 30HV | | Zyplast | |
|--------------------------|---------------|-----|---------|-----|
| | n** | % | n** | % |
| Redness | 129 | 90% | 128 | 89% |
| Pain/Tenderness | 129 | 90% | 123 | 85% |
| Firmness | 127 | 88% | 122 | 85% |
| Swelling | 124 | 86% | 121 | 84% |
| 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 30HV and Zyplast treated sides, were usually mild or moderate in severity, did not require intervention, and lasted 7 days or less.

Juvéderm 30HV was found to provide a more persistent wrinkle correction than Zyplast over the 24-week course of the study. The percentage of subjects who maintained improvement with Juvéderm 30HV at 24 weeks was 90% compared to 40% with Zyplast. At the conclusion of the study, 123 (84%) of 146 subjects expressed a preference for Juvéderm 30HV, while only 15 (10%) expressed a preference for Zyplast, and 8 (5%) had no preference.



Do the injections hurt?

Injections may cause some discomfort during and after the injection. Juvéderm 30HV 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 30HV. 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, 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 INAMED Product Support at (800) 624-4261.

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

M#### .Rev ## MM/YY