

BEFORE YOU BEGIN YOUR PREVELLE® SILK TREATMENTS, PLEASE REVIEW THIS IMPORTANT INFORMATION

INTRODUCTION

The information provided is intended for educational purposes only. It is not a substitute for actual medical consultation and care. Persons requiring diagnosis or treatment, or who have specific questions related to their condition or care, are urged to discuss them with their health care professional.

GLOSSARY OF TERMS

Anesthetic: A compound which reduces the ability to feel pain and/or other sensations; a numbing medication.

Dermal fillers: Substances that are injected just below the surface of the skin to fill in lines, wrinkles, and scars.

Gram positive bacteria: A category of bacteria that all have similar cell walls, a feature that helps determine which antibiotics bacteria are susceptible to. Patients would know or would have been told by their physician if they are allergic to gram positive bacteria, similar to some people with allergies to Penicillin.

Hypertrophic scarring: Raised scarring that stays within the area of the original injury.

Inflammatory reaction: The body's response to trauma or a foreign substance, in this case the injected dermal filler; may result in redness, swelling and tenderness of the skin.

Immunosuppressive therapy: Treatment(s) that lower the body's normal immune response, such as drugs given to prevent transplant rejection.

Keloid formation: Raised scarring that grows beyond the area of the original injury.

Non-steroidal anti-inflammatory drugs: Also known as "NSAIDs;" medicines used to treat pain, redness, swelling, or warmth that can result from a number of conditions including the injections used to administer this product. There are many examples of NSAIDs, including (but not limited to) aspirin and ibuprofen. Some of these are over-the-counter drugs, and some can only be obtained by prescription.

Pigmentation: The color in your skin.

PREVELLE® SILK

What is PREVELLE SILK?

PREVELLE SILK is a colorless hyaluronic acid gel that contains a small quantity of a local anesthetic (Lidocaine) to provide pain relief at the injection site. Hyaluronic acid is a natural substance

found in the human body, which moisturizes (hydrates) and cushions the skin. PREVELLE SILK is naturally broken down by your body over time. Skin testing is not required.

How is PREVELLE SILK used?

PREVELLE SILK is injected into facial skin, using a very fine needle, for correction of moderate to severe wrinkles and folds (e.g. areas around the nose and the mouth). The gel plumps the skin to smooth away wrinkles and folds. Your health care professional will work with you to develop a treatment program to meet your individual needs.

Are there any reasons why I should not receive PREVELLE SILK (Contraindications)?

Your health care professional will determine if there is any reason why you are not an appropriate candidate for PREVELLE SILK. You should be aware that PREVELLE SILK:

- Should not be used in patients with a history of allergies to lidocaine or gram positive bacterial proteins.
- Should not be used in patients with a history of rare, potentially life-threatening allergic reactions or multiple severe allergies.

What should my health care professional WARN me about?

The following are important treatment considerations for you to discuss with your health care professional and understand in order to help avoid unsatisfactory results and complications:

- Patients using aspirin, ibuprofen, and other non-steroidal anti-inflammatory drugs (NSAIDs), or warfarin (a blood thinner) prior to treatment with PREVELLE SILK may notice increased bruising or bleeding at or near the injection sites. Inform your health care professional if you are using these medications to determine when or if you should avoid taking them.
- PREVELLE SILK should be used with CAUTION in patients who are receiving treatment to lower the body's normal immune response (immunosuppressive therapy).
- The safety and effectiveness of PREVELLE SILK for treatment of areas other than facial wrinkles and folds (such as lips) has not been studied in clinical trials.
- The safety of PREVELLE SILK has not been studied in patients with a known potential for excessive scarring (for example, keloid formation and hypertrophic scarring) or disorders involving changes in the color of the skin (pigmentation disorders).
- The safety of PREVELLE SILK has not been studied in patients who are pregnant or breastfeeding or are under 18 years of age.

See other side for consent form



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Notes: _____

What are the risks of using PREVELLE® SILK?

As with all procedures that involve an injection through the skin, there is a risk of infection occurring following treatment.

- The most common symptoms with PREVELLE SILK include temporary injection site reactions such as swelling, pain/tenderness, redness, and lumps/bumps which are normal after hyaluronic acid injections (see Table 1). These reactions are typically mild and go away within 3 days. Some patients may experience one or more of these symptoms for a longer period of time than expected; however, these symptoms typically go away without treatment.

Is the product safe?

The product is safe for most patients. However, patients with certain conditions or allergies should not use this product (see the section “What should my health care professional WARN me about?”). Your health care professional will ask you about your medical history to determine whether PREVELLE SILK is right for you.

Do the injections hurt?

In general, patients may experience varying levels of discomfort. However, PREVELLE SILK contains Lidocaine that helps reduce injection site pain. In a clinical study, 87% of patients experienced significant pain relief at the time of injection with PREVELLE SILK. Your health care professional may choose additional anesthetic to further minimize discomfort.

What did the clinical studies show?

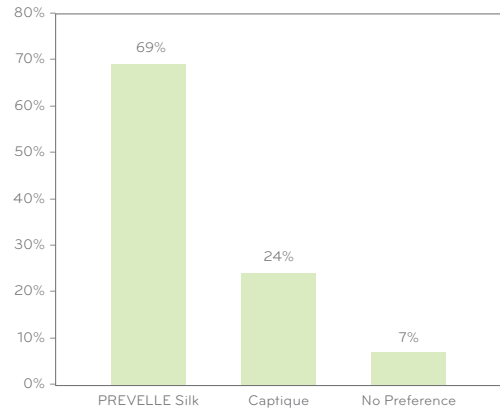
PREVELLE SILK was studied in 45 patients who were injected with PREVELLE SILK on one side of the face and Captique, another hyaluronic dermal filler, on the other side of the face. Local symptoms were reported in diaries for 14 days by the study patients. Most symptoms were mild and went away within 3 days. These results are shown in Table 1 below.

	Injection Site Symptoms (Total Patients = 44 ¹)			
	PREVELLE SILK SIDE		CAPTIQUE SIDE	
Patient Diary Symptoms	Number of patients	Percentage of patients	Number of patients	Percentage of patients
Pain / tenderness	22	50%	20	46%
Lumps / bumps	22	50%	21	48%
Swelling	21	48%	24	55%
Redness	21	48%	24	55%
Bruising	16	36%	20	46%
Peeling	9	21%	5	11%
Other	9	21%	8	18%
Itching	7	16%	7	16%
Skin discolored	4	9%	2	5%

¹One patient did not have any diary data and is therefore disregarded in this table.

In the clinical study, 69% (29) of the 42 patients who responded to the questionnaire preferred treatment with PREVELLE SILK over Captique. Of these 29 patients, 97% (28) preferred PREVELLE SILK because it was less painful (see Figure 1).

FIGURE 1: PATIENT PRODUCT PREFERENCE



What should I ask my health care professional about after my treatment?

Ask when you may resume normal activities such as strenuous exercise, sun exposure or tanning booths, and alcoholic beverages. You may also want to know when it is safe to have laser treatments or chemical peels.

When can I apply make up after the procedure?

You should ask your physician as to when make up can be applied.

How often will I require treatment?

After the initial injection an additional treatment, or touch up, may be needed 1 to 2 weeks later to achieve the desired level of correction. Over time PREVELLE SILK will be broken down naturally by your body, which is why you may want repeat treatments. In general, repeat treatments are needed within 3 to 6 months to maintain the desired result, but the timing of additional treatment varies from person to person.

What other treatments are available?

There are a variety of treatments available for correcting wrinkles and folds, which include other dermal fillers, facial creams, chemical peels, and laser skin surface treatments. Consult with your health care professional to determine which one is right for you.

When should I notify my health care professional?

Be sure to report to your health care professional any redness and/or visible swelling that lasts for more than a few days or any other symptoms that cause you concern. In addition, you may contact Mentor (1-888-704-9193).

For more information, please visit www.prevelle.com

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CONSENT

NOTE: Sign, Remove and file in patient record.

I have read the information titled “About PREVELLE® Silk” 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 PREVELLE® Silk.

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 PREVELLE® Silk.

Signature of Physician or Physician’s Representative _____ Date _____