

Patient Consent for Restylane Injection

Indications. Restylane® is a sterile gel consisting of stabilized hyaluronic acid; Medicis, the manufacturer, states that it is biodegradable, and safely and completely metabolized by the body. Restylane® injections are given to correct facial wrinkles and/or for lip augmentation. Restylane® has been approved by the FDA (Food and Drug Administration) for correction of facial wrinkles in the nasolabial area (nose-lips) and the fold between the cheek and the nose/upper lip (“on-label” use). I understand that the safety and effectiveness of treating facial areas other than the nasolabial folds has not been studied; however, Restylane® has been used to enhance the appearance of lips in over 60 other countries. This “off-label” aspect of the treatment has been explained to me.

Alternatives. There are alternatives to Restylane® injections, including no treatment, collagen for lip or other facial soft tissue augmentation, and cosmetics, Botox, laser skin resurfacing, chemical peels, or plastic surgery for wrinkle reduction.

Results. I understand that the actual degree of improvement cannot be predicted or guaranteed. Furthermore, I understand that the effect will gradually wear off and additional treatments may be necessary to maintain the desired effect.

Side effects and complications include but are not limited to:

- Potential allergic reaction. As with any product, allergies can develop during or after injection.
- Injection site reactions: a lumpy or “thick” feeling at or just under the skin, bruising, redness, itching, pain, tenderness, or slight swelling.
- Injections into the lip area could trigger a recurrence of facial cold sores (Herpes simplex infections) for patients with a history of prior cold sores.

Precautions and contraindications

- Due to the potential for an allergic reaction, Restylane® is not recommended for patients with severe allergies or a history of anaphylaxis.
- The risk of bruising or bleeding may be increased by medications with anticoagulant effects, such as aspirin and non-steroidal anti-inflammatory drugs (e.g., Ibuprofen, Aleve, Motrin, Celebrex), high doses of Vitamin E, and certain herbs (Ginkgo Biloba, St. John’s Wart).
- The safety of Restylane® in pregnant or breast-feeding women has not been established, and is therefore not recommended for these women.

Consent

I understand the need for anesthesia to reduce the discomfort of the procedure and consent to the topical application of anesthetic gel and/or injections for a nerve block or local infiltrative anesthesia. I understand the above, and have had the risks, benefits, and alternatives explained to me, and have had the opportunity to ask questions. No guarantees about results have been made. To the best of my knowledge, I am not pregnant, and I am not breastfeeding. I give my informed consent for Restylane® injections today as well as future treatments as needed.

Patient Signature

Date