



# Restylane® Kysse Fact Sheet

## Enhancing Lip Volume and Minimizing Lines Above the Upper Lip

*Restylane® Kysse* is a new FDA-approved hyaluronic acid (HA) lip filler designed to enhance lip volume and minimize the appearance of fine lines above the upper lip with a natural look and feel.<sup>1</sup> *Restylane Kysse* is the first HA lip filler formulated with XpresHAN Technology™ (pronounced ex-'spre-shan'). XpresHAN Technology™ is designed for excellent tissue integration that allows individuals to maintain their natural-looking expressions.<sup>2,3,4</sup>

### What to expect

- Natural-looking, full, softer, and more kissable lips<sup>5†</sup>
- Improved texture<sup>5†</sup>
- Improved lip color<sup>5†</sup>
- Results clinically proven to last up to 1 year<sup>1,6</sup>

### Comprehensive clinical package

*Restylane Kysse* was evaluated in multiple clinical studies—a pivotal Phase 3 active comparator study, a European supportive active comparator study evaluating *Restylane Kysse* versus the control, as well as a Phase 4 study evaluating naturalness of expression, patient satisfaction, and novel claims around partner satisfaction.<sup>5,6,7</sup>

All commonly reported adverse events (AEs) in the *Restylane Kysse* group were mild in intensity compared to the control group where majority of the late onset events were assessed as moderate in intensity.<sup>7,8</sup> The most common temporary side effects include bruising, masses and nodules, hypersensitivity, redness, and swelling at the injection site.<sup>1</sup> To learn more about serious but rare side effects and full Important Safety Information, visit [RestylaneUSA.com](http://RestylaneUSA.com).

For rewards and savings, visit [AspireRewards.com](http://AspireRewards.com) to join ASPIRE Galderma Rewards.

For more information about *Restylane®*, visit [RestylaneUSA.com](http://RestylaneUSA.com).

†In a Phase 4 clinical study, 59 subjects were treated with *Restylane Kysse* in the lips (n=19) or *Restylane Kysse* in the lips in combination with either *Restylane® Refyne* (n=21) or *Restylane® Defyne* (n=37) in the NLFs or MLs.

Restylane®

KYSSE™

## Important Safety Information

**Indication:** Restylane® Kysse is indicated for injection into the lips for lip augmentation and for correction of upper perioral rhytids in patients over the age of 21.

Restylane Kysse contains traces of gram-positive bacterial protein and is contraindicated for patients with allergies to such material or for patients with severe allergies that have required in-hospital treatment. Restylane Kysse should not be used by patients with bleeding disorders, with hypersensitivity to amide-type local anesthetics, such as lidocaine, or by women who are pregnant or breastfeeding.

Use of Restylane Kysse at the site of skin sores, pimples, rashes, hives, cysts, or infection should be postponed until healing is complete. The most commonly observed side effects are swelling, tenderness, bruising, pain, and redness at the injection site. These are typically mild in severity

and usually resolve within 7 days after treatment. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis and scarring at the injection site. Do not implant into blood vessels. Use with caution in patients recently treated with anticoagulant or platelet inhibitors to avoid bleeding and bruising.

Treatment volume should be limited to 1.5 mL per lip per treatment and 1.0 mL for upper perioral rhytid correction, as greater amounts significantly increase moderate and severe injection site reactions. The safety or effectiveness of treatment in areas other than lips and upper perioral rhytids has not been established in controlled clinical studies.

Restylane Kysse is only available through a licensed practitioner. Complete Instructions for Use are available at [www.RestylaneKysse.com](http://www.RestylaneKysse.com).

**References:** **1.** Restylane Kysse. Instructions for Use. Galderma Laboratories, L.P., 2020. **2.** Data on File. Fort Worth, TX: Galderma Laboratories, L.P. **3.** Segura S, Anthonioz L, Fuchez F, Herbage B. A complete range of hyaluronic acid filler with distinctive physical properties specifically designed for optimal tissue adaptations. *J Drugs Dermatol.* 2012;11(suppl 1):s5-s8. **4.** Philipp-Dormston WG, Wong C, Schuster B, Larsson M, Podda M. Evaluating perceived naturalness of facial expression after fillers to the nasolabial folds and lower face with standardized video and photography. *Dermatol Surg.* 2018;44(6):826-832 **5.** Data on file. 05DF1807 Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2020. **6.** Hilton S, Sattler G, Berg AK, Samuelson U, et al. Randomized, evaluator-blinded study comparing safety and effect of two hyaluronic acid gels for lips enhancement. *Dermatol Surg.* 2018;44:261-9. **7.** Data on file. 43USK1701 Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2019. **8.** Data on file. Restylane Kysse SSED. Fort Worth, TX: Galderma Laboratories, L.P., 2019.