

# Restylane® Portfolio of Hyaluronic Acid (HA) Fillers

**With more than 40 million treatments completed worldwide and counting<sup>1</sup>,**

the *Restylane* line of hyaluronic acid (HA) dermal fillers is the broadest portfolio of fillers in the U.S.<sup>2-7</sup> *Restylane* is the only line of fillers with treatments FDA-approved for both the face and hands. The fillers work by smoothing away facial wrinkles and folds (*Restylane*, *Restylane Lyft*, *Restylane Refyne*, *Restylane Defyne*), enhancing lips (*Restylane*, *Restylane Silk*), smoothing lines around the mouth (*Restylane Silk*), adding lift and volume to the cheeks (*Restylane Lyft*), and reversing the signs of volume loss in the back of aging hands (*Restylane Lyft*).

*Restylane*® LYFT

For cheeks, laugh lines & the backs of hands

*Restylane*® REFYNE

For moderate smile & laugh lines

*Restylane*® SILK

For lips & the lines around them

*Restylane*®- L

For smile lines and lips

*Restylane*® DEFYNE

For deep smile & laugh lines

*Restylane*®

**Restylane** uses two types of technologies to deliver a natural and youthful-looking appearance. Certain Restylane products are formulated with XpresHAN Technology™, which are the only HA filler options proven to maintain natural facial expressions.<sup>3,5,8,9</sup> Select Restylane products are formulated with NASHA Technology, which creates a firmer gel texture that allows for precise injection, leading to a more pronounced lift and smoother skin.<sup>10</sup> All Restylane products deliver results that are natural-looking.<sup>10</sup>

Restylane is formulated with **lidocaine**, which reduces pain during injection and post-injection to improve the treatment experience.<sup>11</sup>



Actual patients. Individual results may vary.

## Restylane Refyne and Defyne

Restylane  
REFYNE

**Restylane Refyne and Restylane Defyne**, introduced in 2017, are FDA-approved to smooth smile and laugh lines.<sup>3,5</sup> They are the only fillers designed with Galderma's unique manufacturing process, **XpresHAN Technology™**, which creates a smooth, injectable gel that can give the skin a natural, soft look, and is proven to maintain natural movement in the lower part of the face.<sup>8</sup> Since the lower part of the face is constantly in motion, it's important to use a filler that supports natural movement and facial expressions.<sup>8,9</sup>

Restylane  
DEFYNE

Both **Restylane Refyne** and **Restylane Defyne** have been used outside the U.S. under the name Emervel since 2011, so safety and efficacy are well-established with more than one million treatments worldwide.<sup>12</sup> Results with **Restylane Refyne** and **Restylane Defyne** are clinically proven to last up to 12 months.<sup>3,5</sup>

## Restylane Lyft

Restylane  
LYFT™

**Restylane Lyft** is the first and only hyaluronic acid filler to be FDA-approved for both the face and hands – the midface/cheek area, nasolabial folds, marionette lines, oral commissures (lines at the corner of the mouth), and the back of the hands.<sup>6,13</sup> **Restylane Lyft** restores volume to the cheeks and hands for a smoother, more youthful looking appearance.<sup>6</sup> One of the most versatile products in the Restylane portfolio, **Restylane Lyft**, formerly known as Perlane, has been on the market for more than 10 years and has a proven track record of safety and efficacy.<sup>14</sup> Results are clinically proven to last up to 18 months in the nasolabial folds, 12 months in the cheeks, and up to 6 months in facial wrinkles and folds the hands.<sup>6</sup>

**Restylane Lyft** was voted one of 2019's "Most Worth It" nonsurgical procedures by RealSelf, with **99 percent** of patients rating the treatment as "Worth It."<sup>15</sup>

## Restylane Silk

Restylane  
SILK

**Restylane Silk** was the **first FDA-approved filler specifically designed for lip augmentation** and the smoothing of wrinkles around the mouth.<sup>7</sup> **Restylane Silk** is designed specifically to provide natural-looking results in these areas, due to its unique formulation.<sup>12</sup> The lip area is the second most common treatment area on the face, and **Restylane Silk** provides a solution for patients interested in subtly enhancing this area.<sup>16</sup> **Restylane Silk** was approved in 2015 and has a proven safety record with results that last up to six months.<sup>7</sup> In 2017, **Restylane Silk** also became the first and only lip filler FDA approved to be injected via cannula, a thin, flexible tube with a small opening that may help minimize patient bruising and downtime.<sup>7,17</sup>

## Restylane-L

Restylane-L

With more than 20 years of clinical legacy, **Restylane** was the world's first hyaluronic acid filler.<sup>18</sup> **Restylane** is FDA-approved to help correct moderate to severe facial wrinkles and folds, including the lines from the nose to the corners of the mouth (nasolabial folds) and the lines from the corners of the mouth to the chin (marionette lines), and for enhancement of the lips.<sup>4</sup>

For rewards and savings, visit [www.AspireRewards.com](http://www.AspireRewards.com) to join ASPIRE Galderma Rewards. For more information about **Restylane®**, the broadest portfolio of HA dermal fillers in the U.S., visit [www.RestylaneUSA.com](http://www.RestylaneUSA.com).

## Important Safety Information

The *Restylane* family of products includes *Restylane*<sup>®</sup>, *Restylane-L*<sup>®</sup>, *Restylane*<sup>®</sup> Lyft with Lidocaine, *Restylane*<sup>®</sup> Silk, *Restylane*<sup>®</sup> Refyne, and *Restylane*<sup>®</sup> Defyne.

### APPROVED USES

*Restylane*<sup>®</sup> and *Restylane-L*<sup>®</sup> are for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. *Restylane*<sup>®</sup> and *Restylane-L*<sup>®</sup> are also indicated for injection into the lips in patients over the age of 21.

*Restylane*<sup>®</sup> Lyft with Lidocaine is for deep implantation into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for cheek augmentation and for the correction of age-related midface contour deficiencies in patients over the age of 21. *Restylane*<sup>®</sup> Lyft with Lidocaine is also indicated for injection into the subcutaneous plane in the dorsal hand to correct volume deficit in patients over the age of 21.

*Restylane*<sup>®</sup> Silk is for lip augmentation and for correction of perioral wrinkles in patients over the age of 21.

*Restylane*<sup>®</sup> Refyne is for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

*Restylane*<sup>®</sup> Defyne is for mid-to-deep injection into the facial tissue for the correction of moderate to severe deep facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

### Are there any reasons why I should not use products within the *Restylane*<sup>®</sup> family? (Contraindications)

To ensure a safe procedure, your doctor will talk to you about your medical history to determine if you are an appropriate candidate for treatment. You should not use products within the *Restylane* family if:

- You have severe allergies with a history of severe reactions (anaphylaxis)
- You are allergic to lidocaine or to any of the gram-positive bacterial proteins used to make hyaluronic acid
- You are prone to bleeding or have been diagnosed with a bleeding disorder

### Are there other precautions that I should discuss with my doctor?

- Tell your doctor if you are breastfeeding, pregnant, or trying to become pregnant. The safety of these products for use during pregnancy, or in women who are breastfeeding, has not been studied
- *Restylane*, *Restylane-L*, *Restylane*<sup>®</sup> Lyft with Lidocaine, *Restylane Refyne* and *Restylane Defyne* are intended to treat facial wrinkles and folds, such as nasolabial folds. *Restylane* and *Restylane-L* are also intended for lip enhancement. *Restylane*<sup>®</sup> Lyft with Lidocaine is also intended for injection in the dorsal hand to correct volume loss. Treatments in other areas of the face or body have not been evaluated in clinical studies.
- The safety and effectiveness of *Restylane*<sup>®</sup> Silk for areas other than the lips and perioral area have not been evaluated in clinical studies.
- Tell your doctor if you have any history of scarring, particularly thick and stiff scars, or any pigmentation (skin color) disorders. These side effects can occur with hyaluronic acid fillers in general.
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Patients who experience skin injury near the site of injection with these products may be at a higher risk for side effects
- Tell your doctor if you are on any medications to decrease your body's immune response (immunosuppressive therapy). Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- Tell your doctor if you are using any "blood thinners" such as aspirin, warfarin, or any other medications that affect bleeding. Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- The use of these products on gel injection sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete. Use of product in these areas could delay healing or make your skin problems worse.
- Tell your doctor if you have diseases, injuries, or disabilities of the hand.

### What are the possible side effects?

The most commonly observed side effects are swelling, redness, pain, bruising, headache, tenderness, lump formation, itching at the injection site, and impaired hand function. These are typically mild in severity and typically resolve in less than 7 days in nasolabial folds and less than 14 days in lips. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis at the injection site.

One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

As with all skin injection procedures, there is a risk of infection.

To report a side effect with any of the *Restylane* products, please call Galderma Laboratories, L.P. at 1-855-425-8722.

The *Restylane* family of products is available only through a licensed practitioner. Complete Instructions for Use are available at [www.RestylaneUSA.com](http://www.RestylaneUSA.com).

<sup>1</sup>Data on file. MA-39680 Report. Fort Worth, TX: Galderma Laboratories, L.P., 2018.

<sup>2</sup>*Restylane*. Instructions for Use. Galderma Laboratories, L.P., 2016.

<sup>3</sup>*Restylane Defyne*. Instructions for Use. Galderma Laboratories, L.P., 2016.

<sup>4</sup>*Restylane-L*. Instructions for Use. Galderma Laboratories, L.P., 2016.

<sup>5</sup>*Restylane Refyne*. Instructions for Use. Galderma Laboratories, L.P., 2016.

<sup>6</sup>*Restylane Lyft*. Instructions for Use. Galderma Laboratories, L.P., 2018.

<sup>7</sup>*Restylane Silk*. Instructions for Use. Galderma Laboratories, L.P., 2017.

<sup>8</sup>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

<sup>9</sup>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(1 Suppl):s5-s8.

<sup>10</sup>Sundaram H, Cassuto D. Biophysical characteristics of hyaluronic acid soft-tissue fillers and their relevance to aesthetic applications. *Plast Reconstr Surg*. 2013;132(4, suppl2):5S-21S.

<sup>11</sup>Data on file. MA-34483 Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2018.

<sup>12</sup>Data on file. Fort Worth, TX: Galderma Laboratories, L.P.

<sup>13</sup>U.S. Food & Drug Administration. Medical Devices, *Restylane Lyft with Lidocaine* - P040024/S099 - <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm609592.htm>. Accessed on August 27, 2018

<sup>14</sup>*PERLANE*<sup>®</sup> Injectable Gel. Summary of Safety and Effectiveness Data (PMA P040024/S6). 2007:1-16.

<sup>15</sup>Data on file. RealSelf Ranks the "Most Worth It" Surgical and Nonsurgical Aesthetic Procedures Based on Consumers' Worth It Ratings. RealSelf. 2019.

<sup>16</sup>Data on file. *Restylane Silk* FDA Approval Press Release. Fort Worth, TX: Galderma Laboratories, L.P., 2015.

<sup>17</sup>U.S. Food & Drug Administration. Medical Devices, *Restylane Silk* Cannula Injection - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040024S096>. Accessed on July 17, 2019.

<sup>18</sup>Data on file. MA-31037 Report. Fort Worth, TX: Galderma Laboratories, L.P., 2016.