

Galderma Receives FDA Approval to Market Restylane® Lyft with Lidocaine to Correct Age Related Volume Loss in the Cheek Area

Restylane® Lyft is first and only FDA-approved filler to treat smile lines and add lift to the cheek area



Photo Caption: Restylane® Lyft with Lidocaine

Fort Worth, Texas (July 2, 2015) – Galderma, a global healthcare company focused on skin health, announced today that it has received U.S. Food and Drug Administration (FDA) approval to market Restylane® Lyft for cheek augmentation and the correction of age-related midface contour deficiencies in patients over the age of 21. Restylane® Lyft, formerly marketed as Perlane-L®, is an injectable gel used to increase volume and smooth wrinkles in the face. With this new indication, Restylane® Lyft is the first and only FDA approved filler indicated to provide fullness to the midface area (cheeks) and to correct and smooth the nasolabial folds (“smile lines”).

“Consumers are looking for safe, high quality products that can deliver natural-looking results. This new indication demonstrates the versatility of Restylane® Lyft and its efficacy in addressing smile lines and restoring structure to the cheeks and midface area,” said Kelly Huang, Ph.D., Vice President and General Manager of Galderma’s Aesthetic and Corrective Business Unit in the U.S. “With more than 15 years of proven safety data and approximately 6 million treatments worldwide, Restylane® Lyft is a trusted, safe and effective product and we are proud to be able to expand our offering to healthcare providers and consumers in the U.S.”

This FDA approval marks the fifth major indication in the U.S. for the Restylane® family of products. Restylane® Lyft joins Restylane®, indicated to correct and smooth smile lines as well as to augment the lips, and Restylane® Silk, the first and only treatment that is approved for lip enhancement and the treatment of wrinkles and lines around the mouth. These brands combined represent the broadest range of dermal fillers with the most FDA approved indications commercially available for healthcare professionals and patients.

“Achieving natural-looking lift in the cheek area is one of the most common requests that I receive from my patients,” said Dr. Robert Weiss, principal investigator of the clinical trial and Director of MD Laser, Skin and Vein Dermatology and Clinical Associate Professor of Dermatology, U of MD. “Restylane® Lyft is an extremely versatile product that has a long, proven history of providing safe, precise and predictable results. The results of this clinical trial show that Restylane® Lyft can provide an effective option for patients when they desire lift -- not just volume -- in their cheeks.”

In a clinical trial involving 200 patients, investigators observed that 88.7% of patients treated with Restylane® Lyft showed an improvement in fullness in the right and left midface areas (combined) at 2 months, and more than half maintained improvement for 12 months¹.



Additionally, 95% of patients reported improvement with the appearance of their midface at 2 months and 73% of patients reported improvement at 12 months². The most common adverse events observed in the trial included: tenderness, redness, bruising, swelling and itching. These events decreased in severity over time and most were resolved within 2 weeks.

The brand name is changing from Perlane-L[®] to Restylane[®] Lyft to help health care providers and consumers understand where the brand fits among the other Galderma products that are based on the core Restylane[®] technology.

For more information about Restylane[®] Lyft and the Restylane family of products, please visit: www.Restylanelyft.com, www.Restylanesilk.com, and www.RestylaneUSA.com

Important Safety Information

Indications: *Restylane[®] Lyft with Lidocaine* is indicated for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as nasolabial folds, and for subcutaneous to supraperiosteal implantation for cheek augmentation and correction of age-related midface contour deficiencies in patients over the age of 21.

Restylane Lyft with Lidocaine should not be used by people with severe allergies, particularly to microorganisms known as gram-positive bacteria, or by people with serious allergies to drugs that have previously required in-hospital treatment. This product should not be used by people with bleeding disorders and should not be injected anywhere except just under the skin. *Restylane Lyft with Lidocaine* should not be used in people with a known allergy to lidocaine.

The most common adverse events after initial treatment include bruising, redness, swelling, pain, headache, tenderness, and itching. Use at the site of skin sores, pimples, rashes, hives, cysts, or infection should be postponed until healing is complete. In these instances, product use could delay healing or make skin problems worse.

This product should not be injected into the blood vessels as it may cause vascular occlusion, infarction, or embolic phenomena.

Restylane Lyft with Lidocaine is available only through a licensed practitioner. Complete Instructions for Use are available at www.RestylaneUSA.com.

About Galderma

Dating back to 1961, Galderma is now present in 80 countries with an extensive product portfolio to treat a range of dermatological conditions. The company partners with health care professionals around the world to meet the skin health needs of people throughout their lifetime. Galderma is a leader in research and development of scientifically-defined and medically-proven solutions for the skin, hair and nails.



Strategic brands in the U.S. include Epiduo®, Oracea®, Clobex®, Differin®, Mirvaso®, MetroGel®, Soolantra®, Vectical®, Tri-Luma®, Cetaphil®, Benzac® Acne Solutions, Restylane®, Restylane® Silk, Perlane®, Dysport® and Sculptra® Aesthetic.

For more information, please visit www.galderma.com and www.galdermausa.com.

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¹ Medicis Midface Volume Scale (MMVS)

² Global Aesthetics Improvement Scale (GAIS)