



Subject: FDA Approves *Restylane*[®] Label Change Based on 18-month Duration Data

STUDY DEMONSTRATED RESTYLANE[®] EFFECT LASTED 18 MONTHS IN 95% OR MORE OF PATIENTS WITH ONE REPEAT INJECTION

As a valued Medicis Aesthetics customer, we want you to be among the first to see new information about *Restylane*[®]. Recent clinical data demonstrated that at 18 months after initial treatment of *Restylane*[®], at least 95% of patients who received a repeat injection had at least a 1 grade of improvement over baseline on the Wrinkle Severity Rating Scale (WSRS). *Restylane*[®] is the only hyaluronic acid dermal filler whose FDA-approved label includes duration data up to 18 months.

Study Description

The duration of *Restylane*[®], effectiveness was demonstrated in a randomized, evaluator-blinded study of 75 patients at three U.S. centers. The study used a bilateral (split-face) comparison design. Patients received treatment in both nasolabial folds at baseline, but were randomized for retreatment in one nasolabial fold at 4.5 months, and retreated in the other side at 9 months. The primary effectiveness endpoint was the number of patients with at least one grade improvement in the WSRS, a five-point scale to measure visual severity of wrinkles where five is the most severe rating (extreme), from baseline as evaluated at the 18 month visit.

The majority of subjects in the study (92.0%) had never received treatment with a dermal filler in the nasolabial folds prior to participating in the study.

Effectiveness Results

At 18 months after the initial treatment, the blinded evaluator determined that:

- 97% of the nasolabial folds retreated at 4.5 months displayed at least one grade WSRS improvement over baseline, with a mean change in wrinkle severity score of 1.7 units.
- 95% of the nasolabial folds retreated at nine months displayed at least one grade WSRS improvement over baseline, with a mean change in wrinkle severity score of 1.6 units.

Safety Results

Injection-site reactions were assessed during the study. The most common adverse events were swelling (24%), bruising (19%), and pain/soreness (5%); none were serious or unexpected.

For more information, please contact your Medicis Aesthetics Sales Specialist or call Medicis Aesthetics at 1-866-222-1480.

Thank you for being a Medicis Aesthetics Customer.

To order *Restylane* please visit www.RestylaneUSA.com or call 877-520-0500.

Safety information

Restylane[®] is indicated for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. The most commonly observed side effects are swelling, redness, pain, bruising, and tenderness at the injection site, which typically resolve in less than seven days. Avoid exposure of the treated area to excessive sun and UV lamp exposure and extreme cold weather until any initial swelling and redness have resolved. Safety has not been established for use during pregnancy, when breastfeeding, or in patients under 18 years.