FDA Filler Update: Revanesse Versa

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Disclosures

Merz – Trainer, Advisory Board
Suneva Medical - Instructor

Will use brand names due to lack of distinguishing generic names
Levels of Evidence and Qualifying Studies (Therapeutic Studies):

I  High-quality, multi-centered or single-centered, randomized controlled trial with adequate power (N ≥ 100); or a systematic review of these studies

II Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies

III Retrospective comparative study; case-control study; or a systematic review of these studies

IV Case series

V Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"
Product Information

• Cross-linked hyaluronic gel
  – 10% not crosslinked

• 25 mg of HA per 1 mL syringe

• Unique features
  – Homogenous uniform spherical particles
  – Balanced with skin water content, less swelling
Gel Particle Shape

Round particle shape may have less inflammatory response
Rheology

- Restylane Versa
- Juvederm Ultra Plus
- Juvederm Ultra

Viscous Liquid Honey-Like

Elastic Gel Jello-Like
Pivotal Study: Versa vs Restylane

- Both **without** lidocaine
- Moderate to severe NLF
- Randomized split face
- Blinded evaluators
- Retreatment allowed
- 24 week endpoint
Results: Primary End Point

PRIMARY EFFICACY ENDPOINT OF STUDY

Mean Change from Baseline at 24 weeks

Revanesse® Versa™
SD = 1.09 ± 0.692

Restylane®
SD = 0.95 ± 0.746

N = 125
P < 0.05

Gold, M. A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel For the Correction of Nasolabial Folds. Data on File.
Results: Secondary End Point

**SECONDARY EFFICACY VARIABLES OF STUDY TREATMENT SUCCESS**

- **Treatment Success**
  - Revanesse® Versa™: 78.4%
  - Restylane®: 72.8%

- **iGAI** (Investigator Global Aesthetic Improvement)
  - Change from Baseline
  - Revanesse® Versa™: 59.2%
  - Restylane®: 47.2%

- **pGAI** (Patient Global Aesthetic Improvement)
  - Change from Baseline
  - Revanesse® Versa™: 44.4%
  - Restylane®: 30.6%

_N = 125_

Gold, M. A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel For the Correction of Nasolabial Folds. Data on File.
Patient Reported Swelling

**Percentage of Study Patients (N) Reported Swelling**

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
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<tbody>
<tr>
<td><strong>Revanesse® Versa™</strong></td>
<td>47.20%</td>
</tr>
<tr>
<td><strong>Restylane®</strong></td>
<td>71.20%</td>
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N = 163

Gold, M. A Multicenter, Double-Blinded, Randomized, Split-Face Study of the Safety and Efficacy of a Novel Hyaluronic Acid Gel For the Correction of Nasolabial Folds. Data on File.
➢ No subjects discontinued the study due to AEs

➢ **TEAEs were reported**
  - 69.9% of Revanesse® Versa™ subjects
  - 84% of Restylane® subjects

➢ Most common injection site TEAEs were:
  - Hematoma (50.3% versa™ /47.2% Restylane®)
  - Swelling (47.2% versa™ /71.2% Restylane®)
  - Pain (38% versa™ /66.3% Restylane®)

➢ Only 2 subjects reported non-injection site TEAEs (headache 3.1%, arthralgia 1.85)
Conclusions

STUDY CONCLUSION

THE TEST PRODUCT, REVANESSE VERSA, IS SAFE AND NON-INFERIOR TO THE COMPARATOR, RESTYLANE, FOR THE CORRECTION OF NASOLABIAL FOLDS.

THE TEST PRODUCT WAS ASSOCIATED WITH LESS SWELLING, PAIN, AND OVERALL SEVERITY OF TREATMENT-EMERGENT ADVERSE EVENTS THAN THE COMPARATOR.
Personal Experience

Compared to Restylane-L (my preferred HA)

- Nice results for lip enhancement
- Harder to inject with 30G x 1 inch needle
- **More** pain (no lidocaine)
  - Lidocaine may be added soon
- Maybe less swelling
- Good price point
FDA Filler Update:
Revanesse Versa

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