**RHA® 3**

**Device Description**

RHA® 3 is a monophasic, sterile, transparent, homogeneous and biodegradable gel implant. It is produced from sodium Hyaluronic Acid (NaHA) with a concentration of 23 mg/g and is contraindicated for patients with a history of allergies to such materials.

**Precautions**

- In order to minimize the risk of potential complications, this product should only be used by experienced healthcare professionals who have been specifically trained in the injection of dermal fillers. The use of dermal fillers in the mid-to-deep dermis requires a deep understanding of facial anatomy and nocx others that are described in the INTENDED USE/INDICATIONS section have not been evaluated in controlled clinical studies.

- As with all intradermal procedures, donor site infection cannot be ruled out. There is a possible risk of eliciting an inflammatory reaction at the injection site.

- When treating patients with a history of inflammatory skin conditions or skin injury is present should be deferred until the underlying process has healed completely after such a procedure.

**Contraindications**

- RHA® 3 is indicated for use in patients with a history of previous herpetic infections and those who are immunocompromised,

**Warnings**

- There were no treatment-related serious AEs.

**Adverse Events**

An adverse event (AE) was defined as a treatment-related event that could result in needle disengagement and/or product leakage at the injection site. All treatment-related AEs were mild or moderate in severity. All treatment-related AEs experienced by both treatment groups were considered to be mild or moderate in severity. All treatment-related AEs were temporally associated with a recent injection of a hyaluronic acid-based dermal filler.

**Study Design**

A controlled, randomized, double-blinded, within-subject, multicenter, prospective clinical study was conducted to evaluate the safety and efficacy of RHA® 3. Subjects were randomly assigned to receive RHA® 3 and control treatment in mid-to-deep dermis for the treatment of moderate to severe nasolabial folds, or to a non-treatment group. The side of the face for each device injection was randomly determined with a coin toss. The control treatment was performed after 2 weeks (3×) with the same device, needle and syringe.

The follow-up period consisted of safety and effectiveness follow-up visits at 12, 24, 36, 52, and 64 weeks after the baseline visit.

Subjects were eligible for optional treatment if necessary at week 24. Additional visits were also optional (begin at week 36, or 52). The follow-up period was at least 2 years.

**Quality Assurance**

All treatment-related AEs were recorded in medical charts, and appropriate training in filler injection techniques, and who are authorized to provide this treatment.

**CLINICAL STUDY**

The safety and effectiveness of RHA® 3 in the correction of moderate to severe nasolabial folds and marionette lines was assessed in a pivotal clinical study described below.

1. **Clinical Evaluation of RHA® 3**

- **Conformity of primary effectiveness endpoints**

The primary effectiveness endpoint was the analysis of non-inferiority of RHA® 3 over control treatment in mid-to-deep dermis for the treatment of moderate to severe nasolabial folds. The study described hereafter.

**Study Design**

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**Quality Assurance**

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Prior to treatment with RHA® 3 the patient should be assessed for indications, risks, and should be informed about the expected treatment results, and expected responses. The patient should be advised of the contraindications for treatment and any associated risks. The patient should be advised of the expected treatment results, and expected responses. If any component of the treatment is not as expected, it is possible to tell when an injection is being made too superficial. If the color of the needle can be seen through the skin during the injection, this means that the injection is too superficial. This should be corrected immediately by making another injection with a different technique and pressure.

The volume to be injected depends on the corrections to be performed, but it is important to not overcorrect. Based on the US clinical study, the optimal volume is 0.015–0.03 cc per wrinkle. More than 90% of the subjects reported to be satisfied or very satisfied with the NLF module of the FACE-Q© questionnaire with the mean score 1. On the Global Aesthetic Improvement (GAI) scale, more than 81% of the subjects and the BLE reported that the NLF treated with RHA® 3 continued to be clinically significant (≥ 1 grade difference from pre-treatment on the WSRS) for more than 78% of the subjects at 64 weeks after initial treatment (Figure 1).

More than 90% of the subjects reported to be satisfied or very satisfied after initial treatment. The rate of satisfaction remained at more than 82% at 64 weeks. The WSRS Responder Rate was ≥ 1 grade difference from pre-treatment on the WSRS) for more than 78% of the subjects at 64 weeks after initial treatment.

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