Safety and effectiveness of SCULPTRA Aesthetic has not been evaluated in subjects with the following:

- History of keloid formation.
- Previous or current treatment with corticosteroids or other immunosuppressants.
- Women who are pregnant, lactating, or breast feeding.
- Subjects who have had or have risks factors for hypertrophic scarring or keloid formation.

PRECAUTIONS

Do not overcorrect (overfill) the contour deficiency of the nasolabial fold contour defect because the depression is expected to gradually improve during several weeks after injection as the treatment effect of SCULPTRA Aesthetic occurs (see INVESTIGATIONAL STUDIES).

A PATIENT'S GUIDE TO TREATMENT WITH SCULPTRA® Aesthetic

Your healthcare provider can help you determine if you might benefit from SCULPTRA Aesthetic and the optimal treatment plan for you.

HOW DOES SCULPTRA AESTHETIC WORK?

SCULPTRA Aesthetic is injected under the surface of skin to fill a space to decrease the appearance of wrinkles and contour deficiencies.

The device contains poly-L-lactic acid (PLLA), a natural biodegradable substance that is produced by living organisms. PLLA is broken down into lactic acid and clean, water-soluble waste products that are naturally eliminated from the body.

After injection, PLLA is processed into collagen fibers that integrate into the skin. These collagen fibers gradually improve the skin’s natural collagen matrix over a period of several months.

SCULPTRA Aesthetic Cosmoplast

The product contains hyaluronic acid which has been derived from fermentation of a bacterial strain of Streptococcus spp. and is produced through a controlled fermentation process. Hyaluronic acid is a naturally occurring substance in the body that provides hydration and lubrication to the skin.

How SCULPTRA Aesthetic is Formulated

SCULPTRA Aesthetic contains: “poly-L-lactic acid” (PLLA), carboxymethylcellulose, and injectable saline solution.

HOW SCULPTRA AESTHETIC WORKS

Poly-L-lactic acid is a biodegradable polymer that stimulates collagen synthesis. It is broken down into lactic acid and clean, water-soluble waste products that are naturally eliminated from the body.

Collagen is one of the most abundant proteins in the body and is the main component of skin. SCULPTRA Aesthetic helps to replace collagen that has been lost due to normal aging or damage.

HOW SCULPTRA AESTHETIC CAN IMPROVE YOUR SKIN

SCULPTRA Aesthetic can improve the appearance of wrinkles and contour deficiencies by stimulating the body’s own natural collagen production.

HOW DO YOU USE SCULPTRA AESTHETIC?

SCULPTRA Aesthetic is administered by a healthcare provider in a single treatment session.

Injections are usually done once every 2-3 months depending on the patient’s needs and the healthcare provider’s recommendations.

The injections are typically delivered to treat the nasolabial fold, cheeks, jaw, temples, and other areas of the face where sagging or lines have developed.

SCULPTRA AESTHETIC (SA) and COSMOPLAST (COS)

The study was designed to compare the safety and effectiveness of SA and COS in reducing the appearance of nasolabial folds.

Study Design

A U.S. study was conducted to compare the safety and effectiveness of SA and COS in reducing the appearance of nasolabial folds.

Study Population

The study included men and women aged 25 to 70 years old with moderate to severe nasolabial folds.

Study Outcome Measures

The primary outcome measure was the reduction in the nasolabial fold depth at 3 months following treatment.

Study Results

The study results showed that SA was more effective than COS in reducing nasolabial fold depth.

Conclusion

SCULPTRA Aesthetic (SA) is a safe and effective treatment for reducing the appearance of nasolabial folds. It is recommended for use by a healthcare provider in a single treatment session.
DO INJECTIONS OF SCULPTRA AESTHETIC HURT?

The studies conducted demonstrated that the treatment was associated with a low rate of injection site reactions, and most side effects were mild and resolved on their own. One small papule required treatment by the health care provider. These side effects, which have been reported with facial injections, can include vision abnormalities, sensory disturbances, and lumps or nodules at the injection site (usually manifest within 3 to 4 months after the treatment). These side effects may require treatment, such as injection of a hyaluronidase agent, systemic corticosteroids, or surgical procedures. If the patient develops worsening or prolonged symptoms or signs or if normal skin coloring does not return, do not continue the injection and seek immediate medical attention.

INSTRUCTIONS FOR USE

- Use SCULPTRA AESTHETIC as directed by the health care provider.
- Do not reuse SCULPTRA AESTHETIC. Each vial is for single use.
- Do not use SCULPTRA AESTHETIC if the bottle has been punctured or tampered with.

Patient Treatment

- If at any time the patient develops unusual pain, vision changes, a severe headache, difficulty walking, face drooping, severe headache, dizziness, or confusion, white appearance of the skin, or sensitivity to light, immediately stop injections and seek medical attention.
- After injection, the treated area should be massaged to distribute the product evenly.
- Do not inject SCULPTRA AESTHETIC if there is evidence of infection or inflammation at the injection site.
- If a lumpy or granulomatous reaction or an abscess develops at the injection site, the health care provider may aspirate the contents.
- Injection site reactions may occur and may be managed by using a nonprescription pain reliever. If you develop a systolic blood pressure higher than 200 mm Hg or a diastolic blood pressure higher than 100 mm Hg, stop injection and seek medical attention immediately.

HOW QUICKLY CAN I GET BACK TO MY DAILY ACTIVITIES?

The studies showed that swelling and bruising typically resolved within 1 week. Depending on the treated area, swelling and bruising may be more pronounced. Pain may be less intense and visible during the first 3 to 4 days after injection and may last for 14 days or longer. For more information on adverse events, see previous section.

HOW LONG DO SCULPTRA AESTHETIC TREATMENT EFFECTS LAST?

The studies showed that the effects of SCULPTRA AESTHETIC were expected to last up to 4 months, but individual patients may experience results for a longer period. The amount of SCULPTRA AESTHETIC and the number of injection sessions will depend on the patient's need. Most patients receive up to 149 injection sessions over an extended treatment period of up to 25 months. These complications, which have been reported with facial injections, can include vision abnormalities, sensory disturbances, and lumps or nodules at the injection site (usually manifest within 3 to 4 months after the treatment). These side effects may require treatment, such as injection of a hyaluronidase agent, systemic corticosteroids, or surgical procedures.