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A PATIENT'S GUIDE TO TREATMENT WITH SCULPTRA® Aesthetic

SCULPTRA Aesthetic (injectable poly-L-lactic acid)

Please review this information carefully before beginning your SCULPTRA Aesthetic Treatment.

This guide is intended to help you become familiar with **SCULPTRA Aesthetic** use, as well as the expected correction, method of injection, post-injection skin care and possible side effects. You may request additional information such as the product label that further describes **SCULPTRA Aesthetic** and its clinical data from your physician. This information is also available on www.sculptraaesthetic.com. *This information is not meant to replace information provided by your healthcare provider. You should always ask your healthcare provider about your treatment and care.*

GLOSSARY

Anesthetic: A substance that causes loss of feeling or awareness. A topical or local anesthetic is a drug that causes temporary loss of feeling in a part of the body where it is placed.

Antiseptic: An agent that kills bacteria or prevents or slows growth of germs.

Biocompatible: A material that does not harm the body.

Biodegradable: A material that can be broken down by the body.

Collagen: The most common protein found in the body. Collagen is used to form a framework to support cell and tissue.

Hypersensitivity: undesirable, discomfort producing reaction; or an allergic reaction.

Injection: Product delivery at the location of a hollow needle tip beneath the surface of the skin.

Immunocompetent: Has a healthy immune system

Keloid formation / Hypertrophic scarring: An overgrowth of scar tissue at the site of a skin injury. Keloids/hypertrophic scars may occur around surgical cuts, traumatic wounds, vaccination sites, burns, or minor scratches. Hypertrophic scarring commonly resolves during the first year after injury; keloid formation most commonly does not resolve.

Lipoatrophy: Loss of fat that is normally under the skin.

Nasolabial fold/ wrinkle: Lines between the nose and the corner of the mouth.

Nodule: Lump under the surface of the skin that is greater than 5 mm, may be visible or not visible, but can be felt when pressed.

Palpable: Able to be touched and felt.

Papule: Lump under the surface of the skin that is less than 5 mm and not visible, but can be felt when pressed.

Patient label: Product information for patients

Peri-orbital: Around the eye.

Poly-L-lactic acid: A man-made lactic acid polymer that is biocompatible and biodegradable.

Product label: Product information for healthcare providers

Side effect: An unwanted event caused by use of the product.

Wrinkle: age-related defect in the contour of the skin surface.

Wrinkle Assessment Score (WAS): a six point photo-numeric scale for the assessment of nasolabial fold wrinkles (see Figure 1).

Wrinkle filler: A product that is injected under the surface of skin to fill a space to decrease the appearance of a cosmetic facial contour deficiency such as facial lines, wrinkles or folds.

WHAT IS SCULPTRA AESTHETIC?

SCULPTRA Aesthetic is a sterile, injectable, biocompatible, biodegradable material that is made of very small particles of a synthetic polymer named "poly-L-lactic acid" (PLLA), carboxymethylcellulose (USP), non-pyrogenic mannitol (USP) and sterile water for injection (USP). While the time needed for **SCULPTRA Aesthetic** to resorb in humans is not known, in rabbits, particles were visible at over one year after injection.

WHO MIGHT BENEFIT FROM TREATMENT WITH SCULPTRA AESTHETIC?

SCULPTRA AESTHETIC is intended for use in people with healthy immune systems as one-time treatment regimen of up to 4 injection sessions that are scheduled about 3 weeks apart for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate. **SCULPTRA Aesthetic** may provide cosmetic correction of facial wrinkles with a Wrinkle Assessment Score of 2, 3, or 4 as shown in the following photos (Figure 1):



Your healthcare provider can help you determine if you might benefit from **SCULPTRA Aesthetic** and the optimal cosmetic correction expected for you. In the US clinical study, optimal correction at 9 weeks after initial injection was most commonly found to be a 0.5 to 1 point decrease (improvement) in WAS.

WHO SHOULD NOT GET SCULPTRA AESTHETIC? (CONTRAINDICATIONS)

You should not get **SCULPTRA AESTHETIC** if you:

- Are allergic to any ingredient of **SCULPTRA AESTHETIC**: "poly-L-lactic acid" (PLLA), carboxymethylcellulose (USP) or non-pyrogenic mannitol (USP).
- Previously had or have risks factors for hypertrophic scarring or keloid formation.

WHAT SHOULD I BE AWARE OF BEFORE RECEIVING SCULPTRA AESTHETIC INJECTIONS (WARNINGS AND PRECAUTIONS)?

In addition to the other information contained in this guide, you should be aware of the following:

- Your healthcare provider needs to know your complete medical history to determine if **SCULPTRA Aesthetic** injection is appropriate. Tell your healthcare provider your complete medical history and if you have an active skin inflammation, an infection or difficulty healing in or near the treatment area.
- The optimal cosmetic correction of your nasolabial folds will depend on your pre-treatment WAS and various other factors. Using the above standard wrinkle assessment score (WAS) photographs, discuss the optimal cosmetic correction that you may expect.
- **SCULPTRA Aesthetic** is intended to be used to achieve optimal cosmetic correction during one to four treatment sessions (typically three) with a minimum of three week intervals between injection sessions. Other filler products should not be directly mixed with **SCULPTRA Aesthetic**.
- **SCULPTRA Aesthetic** should not be injected into sites with active inflammation (e.g., cysts, pimples, rashes or hives). Injection should be deferred until any inflammation has resolved.
- As with all injection procedures, **SCULPTRA Aesthetic** injection carries a risk of infection.
- As with all injections, people with coagulation defects or on concurrent anti-coagulant therapy are at increased risk for hematoma formation, bruising and/or bleeding at the injection site. If you are taking blood thinners or medications that may interfere with clotting of the blood, such as aspirin, you might be more likely to have bruising or bleeding at the injection site.
- **SCULPTRA Aesthetic** has not been systematically evaluated in clinical trials for:
 - Long term safety and effectiveness of **SCULPTRA Aesthetic** beyond 25 months
 - Subjects who are pregnant, lactating, breast feeding, or under 18 years of age. Product approval is based on data from patients between the ages of 26-73. Product use in pediatric patients is not recommended.
 - Subjects with the following: history of keloid formation, hypertrophic scarring, connective tissue disease, active inflammatory conditions, bleeding disorders, active hepatitis, serious abnormalities in laboratory findings, disease such as cancer, stroke and or myocardial infarction, on any immunosuppressive therapy, and or with any other prior or concomitant treatment at the **SCULPTRA Aesthetic** treatment site.
 - Use with local anesthetics, other drug or device use during the same treatment session. No studies of interactions of **SCULPTRA Aesthetic** with drugs or other substances or implants have been made.
 - Use in areas of the body or face other than nasolabial folds. An increased risk of papules and nodules has been reported in published literature after injections in the periorbital area.
- Safety and effectiveness data from clinical trials of **SCULPTRA Aesthetic** in non-Caucasians are limited.
- After treatment with **SCULPTRA Aesthetic**, you should minimize exposure of the treatment area to sun and avoid UV lamp exposure until any initial swelling and redness has resolved.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with **SCULPTRA Aesthetic**, there is a possible risk of increased inflammatory reaction at the **SCULPTRA Aesthetic** implant site. This also applies if **SCULPTRA Aesthetic** is administered before the skin has healed completely after such a procedure.
- **SCULPTRA Aesthetic** should not be injected into the red area of the lip or the skin near the eyes (e.g., eyelid and eyelid folds).

It is unknown whether **SCULPTRA Aesthetic** may be seen during radiologic imaging of your face. If radiologic imaging of your face such as computer tomography (CT) or magnetic resonance imaging (MRI) is to be performed, you should notify the physician about the location of your previous **SCULPTRA Aesthetic** injection.

HOW DOES SCULPTRA AESTHETIC WORK?

Collagen production in the body decreases as you get older and/or are exposed to the sun. Wrinkles are one of the first visible signs of this. **SCULPTRA AESTHETIC** is injected into the deep layer of the skin where collagen naturally exists and is made. **SCULPTRA Aesthetic** works by initially filling a wrinkle with small PLLA beads. As the beads biodegrade the body may produce new collagen where **SCULPTRA Aesthetic** is injected. **SCULPTRA Aesthetic** is injected with multiple small injections using a fine needle in a grid pattern to correct a wrinkle at the nasolabial fold or other facial wrinkles where this injection technique is appropriate:



WHAT WERE THE RESULTS OF THE U.S. CLINICAL STUDY CONDUCTED ON SCULPTRA AESTHETIC?

A U.S. study was conducted to compare the safety and effectiveness of **SCULPTRA Aesthetic** and a control for the treatment of facial wrinkles. The treatment consisted

of one to four visits at three (3) week intervals during which the 233 subjects received treatment with either **SCULPTRA Aesthetic** (n=116) or the control (n=117). Subjects were followed for 13 months after the last treatment. Doctors graded standardized photographs to evaluate the wrinkle reduction effectiveness of both **SCULPTRA Aesthetic** and the control. Safety was evaluated by comparing the number and severity of side effects during the study. Side effects are summarized in the table 1 below.

TABLE 1: NUMBER OF SUBJECTS WITH INJECTION-RELATED SIDE EFFECTS OBSERVED IN SCULPTRA AESTHETIC U.S. CLINICAL STUDY

SIDE EFFECTS TYPE <i>Immediate, as recorded in subject diaries</i>	116 Subjects N (%)
Localized Swelling	94 (81.0%)
Localized Tenderness	94 (81.0%)
Localized Redness	90 (77.6%)
Post-Injection Site Pain	82 (70.7%)
Localized Bruising	75 (64.7%)
Bleeding from Site(s)	39 (33.6%)
Localized Itching	23 (19.8%)
Other	19 (16.4%)
<i>DELAYED, as reported by physicians</i>	
Nodules and papules	20 (17.2%)
Delayed injection site pain*	1 (0.9%)
Average time to appearance after first injection:	
Nodules	209 days
Papules	159 days
Average time of duration:	
Nodules	180 days
Papules	176 days

*one subject reported mild injection site pain approximately 20 months after first injection, no information on outcome was available at the end of the 25 month extension phase study

Most side effects were mild and resolved on their own; one small papule required treatment by the healthcare provider. Five new Sculptra-related events were reported more than 13 months after first injection with **SCULPTRA Aesthetic** in three subjects: 2 papules (1.9%), 1 nodule (0.9%) and 2 injection site pain (0.9%).

Results showed that **SCULPTRA Aesthetic** had effects lasting up to 25 months in some patients for the treatment of nasolabial fold wrinkles as compared to control. Both treatments were well tolerated.

WHAT ADVERSE EVENTS HAVE BEEN REPORTED THROUGH VOLUNTARY POST-MARKETING SURVEILLANCE OF SCULPTRA AND SCULPTRA AESTHETIC USE IN AND OUTSIDE OF THE US?

The most commonly reported serious adverse events were lumps or nodules at the injection site, delayed swollen lumps (granulomas), redness, pain, inflammation, swelling, hypersensitivity and itching. The following events were reported more than 5 times:

- Injection site nodules mostly occurred several months after injection, starting from 1-2 months to 14 months after last **SCULPTRA Aesthetic** administration. In some cases, the nodules went away on their own or after treatment with corticosteroid injections; other nodules lasted up to 2 years. In some cases surgery was required to remove the nodules.
- Serious delayed swollen lumps (granulomas) were reported from several months after injection to more than 1 year after injection. These were treated with corticosteroid injections or surgical procedures. Some cases involving the area under the eyes (infraorbital) or injection in the red area of lips (lip vermilion) required hospitalization. For cases where information was available, the patients were recovering following treatment.
- Serious redness, pain, itching, bruising and heat sensation, were reported within 24 hours after injection. Treatment included corticosteroids, anti-histamines and/or anti-inflammatories. These went away within 7-10 days.
- Serious swelling was reported following injection. Treatment included corticosteroids, anti-histamines and/or anti-inflammatories. Swelling went away within 7-10 days.
- Serious hypersensitivity reactions have been reported, including severe facial swelling (Quincke's edema), with symptoms appearing from 1 day to 1 week after injection. Patients recovered without complication after treatment with intravenous corticosteroids and antihistamines.
- Serious infections at the injection site have been reported, starting from 1 day to one week after injection. Of these cases a few required hospitalization for intravenous antibiotics. All patients recovered or were recovering at the last contact.

Other events that were reported included: application site discharge, fatigue, hypertrophy of skin, injection site atrophy, injection site hardness (induration), lack of

effectiveness, malaise, photosensitive reaction, scar, skin discoloration, skin rash, skin roughness, skin disease inflammation (skin sarcoidosis), skin whitening at the injection site, dilated small blood vessels (telangiectasias), hives (urticaria), visible lumps with or without inflammation or discoloration.

ARE SKIN TESTS NEEDED BEFORE TREATMENT WITH SCULPTRA AESTHETIC?
No skin testing is required prior to use in immunocompetent people with skin that heals normally

ARE THE RESULTS FROM SCULPTRA AESTHETIC IMMEDIATE?

No. Unlike other wrinkle fillers, **SCULPTRA Aesthetic** provides a gradual improvement of the depressed area over several weeks as the treatment effects occur. During the initial treatment session with **SCULPTRA Aesthetic**, a contour defect should be under-corrected, not fully-corrected or over-corrected. It may seem that your treatment worked immediately because of swelling caused by injection and the water used to dilute **SCULPTRA Aesthetic**. This usually resolves in several hours to a few days and may cause the original wrinkle to reappear: you may look as you did before your treatment. Visible wrinkle correction results appear slowly. Your healthcare provider should see you again in three or more weeks to decide if you need additional injections.

HOW OFTEN ARE SCULPTRA AESTHETIC TREATMENTS GIVEN AND HOW MANY TREATMENTS ARE REQUIRED?

Your healthcare provider should see you at approximately three week after each treatment session to assess whether you need additional treatment. You may need one to four treatment sessions (typically three) to achieve the optimal correction possible. The safety and effectiveness of **SCULPTRA Aesthetic** has only been studied in a single treatment regimen of up to four sessions at three week intervals.

HOW LONG DO SCULPTRA AESTHETIC TREATMENT EFFECTS LAST?

In a U.S. clinical study treatment results for some subjects lasted for up to 25 months after the last treatment session. However, the improvement depended on the severity of the nasolabial fold wrinkle (WAS score) that a subject had before treatment. Discuss with your health care provider the optimal cosmetic correction you may expect.

DO INJECTIONS OF SCULPTRA AESTHETIC HURT?

As with any injection, to decrease pain during injection, a topical or a local anesthetic may be applied to the injection area skin before injecting **SCULPTRA Aesthetic**. In U.S. clinical study, subjects recorded pain in diaries: 71% of all treated patients reported some pain after first injection, 14% of subjects had moderate pain. Most pain resolved in less than 24 hours.

WHAT CAN I EXPECT TO HAPPEN AT A TREATMENT SESSION?

Your healthcare provider will answer all of your questions and ask about your medical history to determine if **SCULPTRA Aesthetic** injection is appropriate for you. Tell your healthcare provider about all the medicines you are taking, even over the counter medicines or treatments. You and your healthcare provider will determine if a topical or local anesthetic is needed.

- To prepare for an injection session, all make-up should be removed.
- An injection grid will be decided for each facial wrinkle that is candidate for this treatment and the area to be injected will be cleaned with an antiseptic.
- **SCULPTRA Aesthetic** will be injected in multiple small amounts into the skin using a fine needle in grid pattern.
- After injection, the treated area should be massaged to distribute the product evenly.
- An ice pack should be applied to the treatment area to help reduce swelling unless otherwise directed by your healthcare provider.

WHAT CAN I EXPECT AFTER TREATMENT?

Immediately following a treatment session with **SCULPTRA AESTHETIC**, redness, swelling, pain, bruising or all of these signs can happen in the treatment area. These signs usually go away in a few hours to a few days. Some have been known to last more than 14 days. Your healthcare provider will give you specific post-treatment care instructions. Some specific instructions you should follow after treatment are:

- Massage the treated area for 5 minutes 5 times per day for 5 days after your treatment.
- Within the first 24 hours after your treatment, apply ice or an ice pack wrapped in cloth (avoid putting ice directly on your skin) to the treatment area to help reduce swelling
- Avoid sun and UV sun lamp exposure until swelling and redness have disappeared
- Report any worsening or longer-lasting signs of symptoms to your healthcare provider. As with any injectable wrinkle filler, you can expect injection-related side effects, such as bleeding, tenderness or pain/discomfort, redness, bruising, or swelling. These side effects generally resolve within few days. See table 1 in section "What are the results of the U.S. clinical study conducted on **SCULPTRA Aesthetic**?" above.

HOW QUICKLY CAN I GET BACK TO MY DAILY ACTIVITIES?

Most patients are able to get back to their activities immediately following treatment.

WHEN WILL I BE ABLE TO APPLY MAKE-UP AFTER TREATMENT?

Make-up may be applied a few hours after treatment if there are no complications such as open wounds or bleeding.

WHAT ARE MY OTHER OPTIONS FOR TREATMENT?

There are a variety of dermal fillers available in the US. Prices, safety and effectiveness vary. Consult with your physician to determine which one is right for you.

FOR FURTHER QUESTIONS AND INFORMATION, OR TO REPORT ANY SIDE EFFECTS, PLEASE CALL SANOFI-AVENTIS AT 1-800-633-1610

Patient Prescribing Information as of July, 2009.
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