sculptra®

Poly-L-lactic acid

Sterile

1 Vial

GALDERMA

F50074525D

DEVICE DESCRIPTION

SCULPTRA is an injectable implant that contains microparticles of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. SCULPTRA is reconstituted prior to use by the addition of Sterile Water for Injection (SWFI), USP to form a sterile non-pyrogenic suspension.

COMPOSITION OF SCULPTRA

Each vial of dry powder contains:
150 mg of Poly-L-lactic acid
90 mg of sodium carboxymethylcellulose
127.5 mg of non-pyrogenic mannitol

INDICATIONS FOR USE

SCULPTRA is suitable for increasing the volume of depressed areas, particularly to correct skin depressions, such as in skin creases, wrinkles, folds, scars and for skin aging.

SCULPTRA is also suitable for large volume corrections of the signs of facial fat loss (lipoatrophy).

Injection techniques: The depth of injection and quantity of SCULPTRA used depend on the area to be treated and the result expected.

Over-corrections should be avoided, but if they occur, the area concerned should be thoroughly massaged to ensure proper distribution of the product. Limited correction of the treatment area allows for the gradual improvement of the depressed area over several weeks as the treatment effect occurs.

See **"INSTRUCTIONS FOR USE"** section for additional information.

CONTRAINDICATIONS

- SCULPTRA should not be used in any person who has hypersensitivity to any of the components of the product.

WARNINGS

- Use of SCULPTRA in any person with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled.
- Do not overcorrect (overfill) a contour deficiency because the depression should gradually improve within several weeks as the treatment effect of SCULPTRA occurs (see **INSTRUCTIONS FOR USE**).
- Injection procedure reactions to SCULPTRA have been observed consisting mainly of hematoma, bruising, edema, discomfort, inflammation, and erythema. The most common device related adverse effect was the delayed occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable, asymptomatic and non-visible. Refer to **ADVERSE REACTIONS** for details.
- Special care should be taken to avoid injection into the blood vessels. An introduction into the vasculature may occlude the vessels and could cause skin infarction or embolism.
- Do not inject into the red area of the lip (vermillion). The long term efficacy and safety of SCULPTRA has not been established in the red area of the lip.

PRECAUTIONS

- SCULPTRA should only be used by health care providers with expertise in the correction of volume deficiencies after fully familiarizing themselves with the product, the product educational materials, and the entire instruction leaflet.
- SCULPTRA vials are for single patient and single session use only. Do not reuse or resterilize the vial. Discard immediately after use. Do not use if package or vial is opened or damaged.
- Long-term safety and effectiveness of SCULPTRA beyond two years have not been studied in controlled clinical trials.
- SCULPTRA should be used in the deep dermis or subcutaneous layer. Avoid superficial injections in order to avoid the appearance of early papules or nodules at the injection site, which could be suggestive of improper injection techniques (superficial placement, excessive amount of product, incorrect reconstitution). In addition, massaging the treatment area to ensure proper distribution of the product may also minimize the appearance of papules or nodules.
- Special care must be taken when using SCULPTRA in areas of thin skin, such as the periorbital area. An increased risk of papules and nodules in the periorbital area has been reported (see section "**ADVERSE REACTIONS**"). Refer to the **INSTRUCTIONS FOR USE** regarding injection techniques.
- As with all transcutaneous procedures, SCULPTRA injection carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- As with all injections, patients treated with anti-coagulants may run the risk of a hematoma or localized bleeding at the injection site.
- The safety of SCULPTRA for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- No studies of interactions of SCULPTRA with drugs or othersubstances or implants have been made.
- The safety of using SCULPTRA in patients with susceptibility to keloid formation and hypertrophic scarring has not been established. SCULPTRA should not be used in patients with known history of or susceptibility to keloid formation or hypertrophic scarring.
- The patient should be informed that he or she should minimize exposure of the treatment area to excessive 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, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if SCULPTRA is administered before the skin has healed completely after such a procedure.

ADVERSE REACTIONS

The side effects usually resulting from the injections are transient bleeding from an area the size of the point of the needle or transient pain, localized redness at the injection site, ecchymosis, hematoma.

Based on data obtained through post-marketing surveillance and clinical studies, nodules have also been reported. Subcutaneous papules invisible but palpable, or visible nodules including periorbital nodules or areas of induration have been noted in the injection area and may be due to over-correction. Nodules are occasionally associated with inflammation or discoloration.

The early occurrence of subcutaneous nodules (within 3 to 6 weeks after treatment) may be minimized by adhering to proper dilution and injection technique (e.g., avoiding superficial injections or over-correction). In addition, massaging the treatment area to ensure proper distribution of the product may also minimize the appearance of nodules.

Delayed occurrence of subcutaneous nodules at the injection site, mostly occurred several months post-injection (within 1 to 14 months), with sometimes a prolonged duration of up to 2 years. In some cases, they resolved spontaneously or following treatment with intralesional corticosteroids. Surgical excision of the nodules was sometimes required when they were larger in size, occurring in difficult anatomical regions (e.g. lower eyelid) or persisting after other treatments.

For nodule areas or granuloma formation, the treatment may include multiple intralesional injections of corticosteroids or elective excision.

Other rarely reported adverse events include injection site abscess, injection site infection including cellulites (facial), staphylococcal infection, local infection, granuloma formation, allergic reaction, injection site urticaria, injection site swelling, skin hypertrophy and injection site atrophy, hypersensitivity, angioedema, telangiectasis, skin sarcoidosis.

Scarring and skin discoloration have also been reported.

ANY SIDE EFFECTS OR PRODUCT COMPLAINTS SHOULD BE NOTIFIED TO THE CORRESPONDING ADDRESS:

Galderma Canada Inc.
Thornhill, ON L3T 7W3

INSTRUCTIONS FOR USE

The following supplies are used with SCULPTRA and are to be provided by the end-user:

- Sterile Water for Injection (SWFI), USP
- Single-use 5 mL sterile syringe
- Single-use 1-3 mL (depending on physician practitioner preference) sterile syringes (at least 2)
- 18 G sterile needles (at least 2)
- 26 G sterile needles (several should be available)
- Antiseptic

Reconstitution prior to use

SCULPTRA is reconstituted in the following way:

1. Remove the flip-off cap from the vial and clean the penetrable stopper of the vial with an antiseptic. If the vial, seal, or flip-off cap are damaged, do not use, and call Galderma Canada Inc. at 1-800-467-2081
2. Attach 18 G sterile needle to a sterile single-use 5 mL syringe.
3. Draw 5 mL of SWFI, USP into the 5mL syringe.
4. Introduce 18 G sterile needle into the stopper of the vial and slowly add all SWFI, USP into the vial.
5. Let the vial stand for at least 2 hours to ensure complete hydration; do not shake during this period. SCULPTRA can be stored at room temperature up to 30ºC or refrigerated between 2-8°C during and after hydration.
6. Product should be gently agitated immediately prior to use. Agitate the vial until a uniform translucent suspension is obtained. A single vial swirling agitator may be used. The reconstituted product must be injected within 72 hours of reconstitution. If not used within 72 hours, it must be discarded.
7. Clean the penetrable stopper of the vial with an antiseptic, and use a new 18 G sterile needle to withdraw an appropriate amount of the suspension (typically 1 mL) into a single–use 1-3 mL sterile syringe. Do not store the reconstituted product in the syringe.
8. Replace 18 G needle with a 26 G sterile needle before injecting the product into the deep dermis or subcutaneous layer. Do not inject SCULPTRA using needles of an internal diameter smaller than 26 G.
9. To withdraw remaining contents of the vial, repeat steps 6 through 8.
10. Discard immediately after single session/patient use.

Patient Treatment

1. **Patient Assessment:** A complete medical history should be taken to determine if the treatment is appropriate. Before treatment with SCULPTRA, the patient should be informed completely of the indications, contraindications, warnings, precautions for use, possible side effects and mode of administration of SCULPTRA. Each patient should be informed that the amount of SCULPTRA and the number of injection sessions will depend on the patient's need and the severity of the depressed area. Patients should be informed that more than one injection session is typically necessary to achieve the desired results.
2. **Patient Preparation:** As with all transcutaneous procedures, SCULPTRA injection carries a risk of infection. Standard precautions associated with injectable materials should be followed. As with all injectable products, universal precautions must be observed when there is a potential for contact with patient body fluids. The injection session must be conducted with aseptic technique.
3. **The needle for injections:** SCULPTRA should be injected using a 26 G sterile needle. Do not inject with needles smaller than 26 G and do not bend the needle. To maintain a uniform suspension throughout the procedure, intermittently agitate the product in the syringe. Before initial injection, expel a few drops of SCULPTRA through the attached 26 G needle to eliminate air and to check for needle blockage. If the 26 G needle becomes occluded or dull during an injection session replacement may be necessary. If clogging occurs, remove the needle, expel a small amount of product, attach a new sterile 26 G needle, then expel a few drops of SCULPTRA to eliminate the air and re-check for needle blockage.
4. **The deep dermal plane:** SCULPTRA should be injected into the deep dermis or subcutaneous layer. In order to control the injection depth of SCULPTRA, stretch/pull the skin opposite to the direction of the injection to create a firm injection surface. The 26 G sterile needle, bevel up, should be introduced into the skin at an angle of approximately 30-40 degrees, until the desired skin depth is reached. A change in tissue resistance is felt when the needle crosses from the dermis into subcutaneous layer. If the needle is inserted at too shallow (small) an angle or if the needle tip is not sufficiently advanced, then the needle tip may be in the mid or superficial (papillary) dermis, the needle bevel may be visible through the skin. If product is injected too superficially the injected area will blanch immediately or shortly after injection. If this occurs, the needle should be removed and the treatment area gently massaged. In the event that the blanching does not disappear, the patient should not be re-injected.
5. **Injecting: Threading or Tunneling**

   a) Technique: When the appropriate dermal plane is reached, the needle angle should be lowered to advance the needle in that dermal plane. Prior to depositing SCULPTRA in the skin, a reflux maneuver should be performed to assure that a blood vessel has not been entered. Using the threading or tunneling technique, a thin trail of SCULPTRA should then be deposited in the tissue plane as the needle is withdrawn. To avoid deposition in the superficial skin, deposition should be stopped before the needle bevel is visible in the skin.

   b) Volume per injection: The maximum volume of SCULPTRA per each individual injection should be limited to 0.1 mL – 0.2 mL, spaced at a distance of 0.5 - 1 cm. Avoid overcorrection.

   c) Volume per treatment area: The volume of product injected per treatment area will vary depending on the surface area to be treated. During the initial treatment sessions with SCULPTRA, only a limited correction should be made. In contrast to other wrinkle fillers, SCULPTRA provides a gradual improvement of the depressed area over several weeks as the treatment effect occurs. Additional sessions may be needed to achieve full effect. The total number of injections and thus total volume of SCULPTRA injected will vary based on the surface area to be corrected, not on the depth or severity of the deficiency to be corrected.
6. **Injecting: Depot**

   a) Technique: The depot technique is most appropriate for injections into areas of thin skin at the level of the temples. When using this technique, SCULPTRA is injected as a small bolus deep to the temporalis muscle. Intramuscular injection should be avoided.

   b) Volume per injection: The volume of SCULPTRA should be reduced to approximately 0.05 mL/injection. Following each injection, the area should be massaged.
7. **Massage during the injection session:** The treatment areas should be periodically massaged during the injection session to evenly distribute the product.
8. **Degree of correction:** The depressed area should never be overcorrected (overfilled) in an injection session. Limited correction of the treatment area allows for the gradual improvement of the depressed area over several weeks as the treatment effect occurs. Typically, patients will experience some degree of edema associated with the injection procedure itself, which will give the appearance of a full correction by the end of the injection session (within about 30 minutes). The patient should be informed that the injection-related edema typically resolves in several hours to a few days, resulting in the 'reappearance' of the original contour deficiency.
9. **Post-treatment care:** Immediately following an injection session with SCULPTRA, redness, swelling, and/or bruising may be noted in the treatment area. Refer to **ADVERSE REACTIONS** section for details. After the injection session, an ice pack (avoiding any direct contact of the ice with the skin) should be applied to the treatment area in order to reduce swelling and/or bruising.

   It is important to thoroughly massage the treatment area to evenly distribute the product. The patient should periodically massage the treatment areas for five minutes, five times per day for five days after the injection session to promote a natural looking correction.

   SCULPTRA may be visualized with ultrasound imaging and MRI. It is not observed with CT scans and radiography.
10. **Treat, Wait, Assess:** During the first injection session with SCULPTRA, only a limited correction should be made. Do not overcorrect (overfill). The patient should be evaluated no sooner than four weeks after the injection session to determine if additional correction is needed. The original skin depression may initially reappear, but the depression should gradually improve within several weeks as the treatment effect of SCULPTRA occurs. The patient should be advised of the potential need for additional injection sessions at the first consultation.

SPECIAL STORAGE CONDITIONS

SCULPTRA powder should be stored at controlled room temperature (15-30°C) away from heat.

Upon reconstitution, SCULPTRA can be stored up to 72 hours at room temperature or refrigerated. Do not freeze.

HOW SUPPLIED

SCULPTRA is supplied as a sterile freeze-dried preparation powder for injection in a clear glass vial, which is sealed by a penetrable stopper, covered by an aluminum seal with a flip-off cap. Each carton of SCULPTRA contains one vial.

IF THE VIAL, SEAL, OR FLIP-OFF CAP ARE DAMAGED, DO NOT USE, AND CONTACT Galderma Canada Inc. (SEE CONTACT INFORMATION PROVIDED ABOVE).

After use, treatment syringes and needles may be potential biohazards. Discard the needles and syringes in a safe disposal container.

This leaflet was last approved on February 11, 2011

Rev. 06/15

Manufacturer:
Q-Med AB Seminariegatan 21, SE-752 28 Uppsala, Sweden

Distributor:
Galderma Canada Inc Thornhill, ON L3T 7W3

Made in Italy

? ☎ **1-800-467-2081** 89028131

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89028131 (int. version 8) | 25 GIU 2015

TYPE OF MATERIAL:	DESCRIPTION:				COUNTRY:	LOGO VERSION:
LEAFLET	SCULPTRA 1 VIAL				CANADA	//
MIN. FONT SIZE:	CODE:	VERSION:	OLD CODE :	DIMENSIONS mm:	COLOURS N°:	
5.5 pt	89028131	6 a	89025875	125 x 420	1	BLACK