SCULPTRA ®

Poly-L-lactic acid

Sterile

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 5-8 mL Sterile Water for Injection (SWFI), USP to form a sterile non-pyrogenic suspension.

As an optional means to provide pain relief during the injection procedure, an additional 1 mL of sterile 2% (20 mg/ml) lidocaine solution may be added to the vial of reconstituted product prior to injection for a final volume of 6–9 ml (refer to Section "**INSTRUCTIONS FOR USE**").

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 in patients over the age of 21.

SCULPTRA is also suitable for large volume corrections of the signs of facial fat loss (lipoatrophy) in patients over the age of 21.

Injection techniques: SCULPTRA is injected into the deep dermis or subcutaneous layer with a 25G or 26G needle with sterile single-use syringes. Inject the product slowly and apply the least amount of pressure necessary. The depth of injection and quantity of SCULPTRA used depend on the area to be treated and the result expected.

Because the treatment effects for SCULPTRA appear gradually over a few weeks, for the first treatment session a limited correction should be performed. The patient should then be re-evaluated no sooner than four weeks post-treatment to determine if additional correction is needed.

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

CONTRAINDICATIONS

- Do not use in patients with a history of hypersensitivity to any of the components of the product.
- Do not use reconstituted SCULPTRA product supplemented with lidocaine in patients with a history of hypersensitivity to lidocaine or other amide-type local anaesthetics.
- Do not use in patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- Do not use when there is active disease, such as inflammation (skin eruption such as cysts, pimples, rashes or hives), infection or tumours, in or near the intended treatment site, until the underlying process has been controlled.

WARNINGS

- SCULPTRA should be used in the deep dermis or subcutaneous layer.
- Improper injection techniques such as superficial placement, excessive amount of product or incorrect reconstitution may lead to appearance of papules or nodules at the injection site. Massaging the treatment area to ensure proper distribution of the product may minimise the appearance of such papules or nodules.
- Special care should be taken to avoid injection into the blood vessels. Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction.
- Localized ischemia/necrosis and scarring may occur after injection in or near vessels. Special caution should be taken if the patient has undergone a prior surgical procedure in the planned treatment area. Areas with limited collateral blood flow has an increased risk of ischemia. Aspiration prior to injection is recommended.
- Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures.
- Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure.
- Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.
- Do not overcorrect (overfill) a contour deficiency, because the depression should gradually improve within several weeks as the treatment effect of SCULPTRA occurs. If an overcorrection occurs, the area concerned should be thoroughly massaged to ensure proper distribution of the product (see **INSTRUCTIONS FOR USE**).
- Safety and efficacy of SCULPTRA has not been established in the red area of the lip. Do not inject into the red area of the lip (vermillion).
- SCULPTRA vials are for single patient and single session use only in order to avoid contamination. Do not re-use the vial and do not re-sterilise the vial. Discard immediately after use. Do not use if package or vial is opened or damaged.

- Always reconstitute the powder with sterile water for injection.

PRECAUTIONS

- In order to minimize the risks of potential complications (such as formation of papules/nodules, perforation of vessels, or trauma to nerves and other vulnerable structures), this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
- Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.
- Long-term safety and effectiveness of SCULPTRA beyond two years have not been studied in controlled clinical trials.
- As with all transcutaneous procedures, SCULPTRA injection carries a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be followed.
- Patients with bleeding disorders or patients using substances that affect platelet function, thrombolytics or anticoagulants may, as with any injection, experience increased bruising or bleeding at injection site.
- Interactions of SCULPTRA with previous implants, or concomitantly administered drugs other than lidocaine, have not been studied. Reconstituted SCULPTRA suspension mixed with devices or drugs other than lidocaine has not been studied.
- Injection too superficially, or in facial areas with limited soft tissue support or soft tissue cover, or thin skin, such as the periorbital area, may result in contour irregularities and palpable lumps. (see section "**ADVERSE REACTIONS**"). Refer to the **INSTRUCTIONS FOR USE** regarding injection techniques.
- Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.
- This product should be used with caution in patients on immunosuppressive therapy.
- Patients with unattainable expectations are not suitable candidates for treatment.
- The safety of SCULPTRA for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- Formation of keloids or hypertrophic scars may occur after dermal filler injections including SCULPTRA injections.
- The patient should avoid excessive sun, UV lamp exposure and extreme temperatures 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.

In addition, the following precautions should be observed if lidocaine is added to the reconstituted SCULPTRA suspension prior to treatment:

- Only a sterile lidocaine solution should be added to the reconstituted SCULPTRA suspension just before the injection procedure. See the section "**INSTRUCTIONS FOR USE**" for additional procedural information.
- Consider safety risks associated with the use of lidocaine, including possible toxic effects in patients with increased sensitivity and accumulating levels of lidocaine if used concurrently with other administration. For specific safety information, refer to the product labelling for the lidocaine solution used.

ADVERSE REACTIONS

Anticipated injection-related reactions

The anticipated injection related reactions include transient bleeding from the needle stick, pain, localised redness, bruising, haematoma, or oedema, which generally resolve within 2–6 days.

Post-Marketing Surveillance

The following post marketing adverse events have been reported from worldwide sources after treatment with SCULPTRA (non-exhaustive list) in decreasing order of frequency:

Papules/nodules; Swelling/oedema; Mass/induration; Device ineffective; Pain/tenderness; Erythema; Granuloma/foreign body reaction; Bruising/bleeding; Inflammation; Eye disorders including dry eyes, eye pain, eye swelling, eyelid ptosis, eyelid oedema, increased lacrimation, and visual impairment such as blindness, blurred vision, and reduced visual acuity; Other injection site reactions and skin reactions including burning sensation, dryness, exfoliation, irritation, nerve injury, discomfort, and warmth; Infection/abscess including pustule, cellulitis and purulent discharge; Discoloration/pigmentation; Neurological symptoms including facial paralysis, hypoaesthesia, tremor and paraesthesia; Pruritus; Hypersensitivity/angioedema; Asymmetry/deformity including cutaneous contour deformity; Scar/scab/skin atrophy; Rash and Ischemia/necrosis including pallor, ulcer and vascular occlusion; Acne; Urticaria; Dermatitis; Device dislocation; Blisters/vesicles; Reactivation of herpes infection;Muscle disorders including muscle twitching and muscular weakness; Discharge; Capillary disorders such as telangiectasia; Encapsulation; Extrusion of device; Other dermatological events including localised alopecia, skin tightness and skin wrinkling; Non-dermatological events including anxiety, arthralgia, chills, depression, diarrhoea, dizziness, dyspnoea, emotional distress, fatigue, headache, influenza like illness, insomnia, malaise, nausea, pyrexia, sinusitis, and vomiting.

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 discolouration.

The early occurrence of subcutaneous nodules at the injection site (within 3–6 weeks after treatment) may be minimised by adhering to proper dilution and injection techniques (see sections "**INSTRUCTIONS FOR USE**" and "**INDICATIONS FOR USE**").

Delayed occurrences of subcutaneous nodules at the injection site (within 1–14 months post-injection) have been reported with sometimes a prolonged duration of up to 2 years.

For nodular areas or late granuloma formation, in some cases, they resolved spontaneously or

following treatment with multiple intralesional injections of corticosteroids and/or antineoplastic agents (e.g. 5-fluorouracil). 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.

Vascular compromise may occur due to an inadvertent intravascular injection or as a result of vascular compression associated with implantation of any injectable product. This may manifest as blanching, discolouration, necrosis or ulceration at the implant site or in the area supplied by the blood vessels affected; or rarely as ischemic events in other organs due to embolisation. Rare but serious cases of ischemic events associated with temporary or permanent vision impairment, blindness, cerebral ischaemia or stroke have been reported following facial aesthetic treatments.

For patients who have experienced clinically significant reactions, a decision for retreatment should take into consideration the cause and significance of previous reactions.

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

Galderma Canada Inc.
Thornhill, ON L3T 7V9

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 or 25 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

Please note that the following steps 2–5 should be performed, irrespective of the final desired reconstitution volume. This, to ascertain air pressure relief in the vial and to allow for sufficient head-space when shaking the vial to dissolve the content.

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 the 18G sterile needle into the stopper of the vial, find the open slit in the stopper and slowly add all SWFI, USP into the vial letting the water flow on to the inner wall of the vial. Remove the syringe and needle.

5. Shake the vial vigorously by hand or by single vial swirling agitator for about 1 minute to dissolve the excipients. Inspect the vial for any remaining lumps, and if needed shake more. A translucent suspension with some foam on the top will be obtained.

6. If desired, add up to 3 ml of additional SWFI, USP using the syringe and a new 18G needle. Remove the syringe and needle. Shake again in order to get a homogenous suspension.

7. Following reconstitution, SCULPTRA can/ should be used immediately or may be stored for up to 72 hours prior to injection. Refrigeration is not required.

8. 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.

9. Clean the penetrable stopper of the vial with an antiseptic and use a new 18G sterile needle to withdraw an appropriate amount of the suspension (typically 1 ml) into a single-use 1 ml sterile syringe. Tilt the vial horizontally and withdraw suspension from the lower lateral of the vial to avoid withdrawing foam. Do not store the reconstituted product in the syringe.

10. Replace the 18G needle with a 25G or 26G 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 25G or 26G.

11. To withdraw remaining contents of the vial, repeat steps 8 through 9. Do not inject the foam.

12. Discard immediately after single session/patient use.

Optional addition of local anaesthetic lidocaine.

If desired for the purpose of providing pain relief during the injection procedure, after completion of step 6 of the Reconstitution instructions described above, add another 1 ml of 2% (20 mg/ml) lidocaine solution to the vial immediately prior to injection. Clean the penetrable stopper of the vial with an antiseptic, add the lidocaine solution using a single-use 1 ml sterile syringe and an 18G sterile needle and shake the suspension. Go to step 7 of the Reconstitution instructions described above and complete the procedure. It should be noted that the addition of lidocaine according to these instructions will lead to a final vial volume of 6–9 ml with a lidocaine concentration of 3.3–2.2 mg/ml.

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 or 25 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 needle to eliminate air and to check for needle blockage. If the 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 or 25 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 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. In order to minimize the risks of potential complications, inject the product slowly and apply the least amount of pressure necessary. 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: Bolus**

a) **Technique**: When using this technique, SCULPTRA is injected as a small bolus into the deep dermis or subcutaneous layer. 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 (in a suitable cloth, 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(s) to evenly distribute the product (use of an appropriate cream may help to reduce the friction on the skin surface during massaging). 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.

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 two vials.

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.

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

Distributor:
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Made in Italy

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