Sculptra®

Poly-L-lactic acid

Description

Sculptra is a poly-L-lactic acid implant in the form of a sterile non-pyrogenic suspension, which is reconstituted from a sterile dry powder by the addition of sterile water for injection. This suspension contains microparticles of poly-L-lactic acid, a crystalline form of polylactic acid. Poly-L-lactic acid is a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family.

Sculptra dry powder is supplied after aseptic filtration sterilization in a sterile elongated clear glass vial with an aluminium ring at one end, which is hermetically sealed by a rubber bung, covered by a flip-off cap.

Sculptra dry powder is reconstituted with 5–8 ml of sterile water for injection 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 “Treatment procedure”).

Composition:

Each vial of dry powder contains:

Poly-L-lactic acid	150 mg
Sodium carboxymethylcellulose	90 mg
Non-pyrogenic mannitol	127.5 mg

DEVICE CLASSIFICATION

Class III medical device containing a scheduled substance (prescription medicine).

INTENDED USE

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

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

Injection technique: Sculptra is injected into the deep dermis, subcutaneous layer or into the supraperiosteal plane with a 25G or 26G needle with sterile single-use syringes. 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 section "Treatment procedure" for additional information.

CONTRAINDICATIONS

- Do not use in patients with a history of hypersensitivity to any of the constituents 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.

WARNING

- Sculptra should only be used in the deep dermis, subcutaneous layer or in the supraperiosteal plane. 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.
- This product must not be injected intramuscularly or intravascularly. Localised superficial necrosis and scarring may occur after injection in or near vessels. It is thought to result from the injury, obstruction, or compromise of blood 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 ischaemia. Aspiration prior to injection is recommended.

- Unintentional introduction of soft tissue fillers into the vasculature in the face may lead to embolisation, occlusion of the vessels, ischaemia, necrosis or infarction at the implant site or in the area supplied by the blood vessels affected. Rare but serious adverse events include temporary or permanent vision impairment, blindness, cerebral ischaemia or cerebral haemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if any of the following symptoms occurs, 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 over-correct (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.
- 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. Discard immediately after use. Do not reuse or do not resterilize the vial. Do not use if package or vial is opened or damaged.
- Always reconstitute the powder with sterile water for injection.

PRECAUTIONS

- 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.
- This product should only be used by health care practitioners who have appropriate training, experience, and knowledge about the product use and the anatomy at and around the site of injection in order to minimise the risks of potential complications (such as formation of papules/nodules, perforation of vessels, or trauma to nerves and other vulnerable structures).
- Injection procedures are associated with 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, haematoma or localised 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 thin skin, such as the periorbital area or peri-oral areas, may result in contour irregularities and palpable lumps.
- 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.
- Formation of keloids or hypertrophic scars may occur after dermal filler injections including Sculptra injections.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is performed 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.
- The patient should avoid excessive sun, UV lamp exposure and extreme temperatures until any initial swelling and redness has resolved.
- The safety of Sculptra for use during pregnancy, in breastfeeding women or in patients under 18 years has not been established.

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 “Treatment procedure” 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 EVENTS

The anticipated injection-procedure 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). The rate of reporting is based on the number of estimated treatments performed.

1/1 000 – 1/10 000	Papules/nodules; Swelling/oedema; Mass/induration; Device ineffective.
1/10 000 – 1/100 000	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.
<1/100 000	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; 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; Other dermatological events including localised alopecia, skin tightness and skin wrinkling.

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 "Treatment procedure" and "Intended 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.

For reporting of adverse events, contact your local Galderma representative or distributor for this product.

TREATMENT PROCEDURE

Reconstitution instructions

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.

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

2. Attach an 18 G sterile needle to a sterile single use 5 mL syringe.

3. Draw 5 mL of sterile water for injections into the 5 mL syringe.

4. Introduce the 18 G needle into the stopper of the vial, find the open slit in the stopper and slowly add all sterile water for injection 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 sterile water for injection using the syringe and a new 18G needle. Remove the syringe and needle. Shake again in order to get a homogenous suspension.

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

7. Product should be gently agitated immediately prior to use. Agitate the vial until a homogenous translucent suspension is obtained. A single vial swirling agitator may be used. As it is a single use vial, discard any material remaining after use or after 72 hours following reconstitution (See “Shelf life and storage conditions”).

8. Clean the penetrable stopper of the vial with an antiseptic, and use a new 18 G needle to withdraw the 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 reconstituted product in the syringe.

9. Replace the 18 G needle with a 25 G or 26 G sterile needle, before injecting the product into the deep dermis, subcutaneous layer or into the supraperiosteal plane. Do not inject Sculptra using needles of an internal diameter smaller than 25 G or 26 G.

10. To withdraw remaining contents of the vial, repeat steps 7 through 9. Do not inject the foam.

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

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 based on the mode of action of the product.

Make sure to work under aseptic and hygienic conditions. Clean the injection site with an antiseptic.

Sculptra powder should be reconstituted extemporaneously with 5–8 ml of sterile water for injection. Prior to injection, optionally add another 1 ml of local anaesthetic lidocaine (20 mg/ml) to the vial.

Sculptra should be injected into the deep dermis or subcutaneous layer. Depending on the anatomical area and goals of treatment, a supraperiosteal administration may be appropriate.

Perform the injections using 25G or 26G needles. To avoid breakage of the needle, do not attempt to bend it before or during treatment. If the needle gets bent, discard it and complete the procedure with a replacement needle.

To maintain a homogeneous suspension throughout the procedure, intermittently agitate the product in the syringe. Before initial injection, expel a few drops of the product 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 needle, then expel a few drops of Sculptra to eliminate the air and re-check for needle blockage.

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.

During the first treatment session with Sculptra, only a limited correction should be made. The patient should then be evaluated at no sooner than four weeks post-treatment to determine if additional correction is needed.

After the injection session, ice (in a suitable cloth, avoiding any direct contact 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 treated 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 treated areas for five minutes, five times per day for five days after the treatment to ensure a natural-looking correction.

Sculptra may be visualised with ultrasound imaging and MRI. It is not observed with CT scans and radiography.

MODE OF ACTION

Sculptra consists of a suspension of solid poly-L-lactic particles with a defined narrow particle size distribution and slow degradation kinetics due to high molecular weight and high degree of crystallinity. The particle size and narrow particle size distribution enables the injection of the poly-L-lactic particles into the deep dermis, subcutaneous layer or into the supraperiosteal plane,

where they provide soft tissue augmentation that will improve over the course of a few weeks, as the microparticles are gradually surrounded by host connective tissue.

STORAGE CONDITIONS

Do not use after expiry date indicated on the package or if the expiry date or lot number is missing or illegible.

Sculptra powder should be stored at room temperature away from heat (maximum 30°C). Upon reconstitution, Sculptra can be stored up to 72 hours at 2 to 8°C in the refrigerator or at room temperature up to 30°C.

Do not freeze.

After patient use, treatment syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local requirements.

PATIENT INSTRUCTIONS

For reporting of adverse events, contact your local Galderma representative or distributor for this product.

Manufacturer

Q-Med AB

Seminariegatan 21

SE-752 28 Uppsala

Sweden

Tel: +46(0)18 474 90 00

www.galderma.com, e-mail: info.q-med@galderma.com

Sponsor

Galderma Australia Pty Ltd

Level 18, 1 Denison Street, North Sydney NSW 2060

Australia

Phone 1800 800 765

New Zealand Distributor:

Healthcare Logistics

58 Richard Pearse Drive, Airport Oaks Auckland, New

Zealand. Phone 0800 174 104

For any information about this product, please contact your local representative.

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