Sculptra®

Poly-L-lactic acid

GALDERMA

COMPONENTS

SCULPTRA® is a poly-L-lactic acid implant in the form of a sterile apyrogenic suspension, which is reconstituted from a sterile dry powder by the addition of sterile water for injections (European Pharmacopoeia). This suspension contains microparticles of poly-L-lactic acid, the crystalline form of polylactic acid, carboxymethylcellulose and non-pyrogenic mannitol. Poly-L-lactic acid is the crystalline form of polylactic acid. Poly-L-lactic acid is a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family.

PRESENTATION

The **SCULPTRA®** sterile freeze-dried powder is supplied in an elongated clear glass vial with an aluminium ring at one end, which is hermetically sealed by a rubber stopper, covered by a flip-off cap.
The contents of the vial are reconstituted prior to use with 5 ml of sterile water for injections to form a sterile non-pyrogenic suspension.
Sterile: prepared aseptically

COMPOSITION OF SCULPTRA®

Each vial contains:
150 mg Poly-L-lactic acid
90 mg Sodium carboxymethylcellulose
127.5 mg Mannitol

DEVICE CLASSIFICATION

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

INTENDED USE

Increase the volume of depressed areas, particularly to correct skin depressions.

OTHER USES

Large volume restoration and/or correction of the signs of facial fat loss (lipoatrophy) including HIV patients treated with antiretroviral drugs.

CONTRAINDICATIONS

SCULPTRA® should not be used in any person who has hypersensitivity to any of the components of the product. Do not use in the case of acute or chronic skin disease (infection or inflammation) near the area to be treated. Treatment should be deferred until the inflammation or infection has been controlled.

WARNING

SCULPTRA® should only be used subcutaneously or deep intradermally. 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.
Do not inject into a blood vessel, to avoid the risk of skin infarction or embolism of a blood vessel. The fluidity of **SCULPTRA®** makes it easy to aspirate with the syringe before injection, to ensure that the needle is not in a blood vessel.
Do not over-correct a contour deficiency, because the depression should gradually improve within several weeks as the treatment effect of **SCULPTRA®** occurs.
Caution must be taken when injecting **SCULPTRA®** in areas of thin skin, especially in the peri-orbital and the peri-oral areas. An increased risk of papules and nodules in the periorbital area has been reported. Refer to instructions for use for information regarding injection techniques.
Do not inject into the red area of the lip (vermillion).
Always mix the powder with sterile water for injections (sterile water for injections: in compliance with European Pharmacopoeia).
For implantation of **SCULPTRA®**, use 26 G needles with single-use sterile syringes.
Single patient and single session use only: Discard immediately after use. Do not reuse or do not resterilize the vial. Do not use if package or vial is opened or damaged.

PRECAUTIONS FOR USE

The injection site should be cleaned with an antiseptic and free from inflammation or infection.
As with all injections, patients treated with anti-coagulants may run the risk of a haematoma or localized bleeding at the injection site.
The safety of **SCULPTRA®** for use during pregnancy, in breastfeeding women or in patients under 18 years has not been established.
No studies of interactions of **SCULPTRA®** with drugs or other substances or implants have been made.
SCULPTRA® should only be used by healthcare providers with expertise in the correction of volume defects after fully familiarizing themselves with the product, the product education materials and its complete instruction leaflet.
The safety of using **SCULPTRA®** in patients with susceptibility to keloids
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 exposure of the treated area to excessive sun, UV lamp exposure until any initial swelling and redness has resolved should be minimised.
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.

SIDE EFFECTS OF THE TREATMENT

The adverse reactions considered to be possibly or probably related to the administration of poly-L-lactic acid have been obtained from clinical studies or detected from post-marketing surveillance and literature reports.

Injection site reactions
Injection site haemorrhage
Injection site pain
Injection site induration
Injection site swelling

Immune system disorders
Hypersensitivity
Angioedema
Skin sarcoidosis

Infections and infestations
Injection site infection, including cellulitis (facial), staphylococcal infection Injection site abscess

Skin and subcutaneous tissue disorder
Bruising
Haematoma
Injection site atrophy, skin hypertrophy
Injection site erythema
Injection site urticaria
Telangiectasis
Subcutaneous papules, non visible, typically palpable, asymptomatic
Visible nodules, including periorbital nodules, with or without inflammation or discoloration.
Granuloma
Scarring
Skin discolouration
The early occurrence of subcutaneous nodules at the injection site (within 3 to 6 weeks after the treatment) may be minimized by adhering to proper dilution and injection techniques (refer to Warning). Delayed occurrence of subcutaneous nodules at the injection site (within 1 to 14 months post injection) with sometimes a prolonged duration of up to 2 years. In some cases, they resolved spontaneously or following treatment with intralesional corticosteroids. Surgical excision was sometimes required when the nodules were larger in size, occurring in difficult anatomical regions (e.g., lower eyelid) or persisting after other treatments.

TREATMENT OF OVERCORRECTION

Small, invisible but palpable, or visible 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 occurrence of nodules may be minimized by adhering to proper 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.

INSTRUCTIONS FOR USE

Reconstitution prior to use

The contents of the vial are reconstituted with 5 mL of sterile water for injections.
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 is damaged, do not use, and contact Galderma (see contact information provided below).
2. Attach an 18 G sterile needle to a sterile single use 5mL syringe.
3. Draw 5 ml of sterile water for injections (sterile water for injections: in compliance with European Pharmacopoeia) into the 5 mL syringe.
4. Introduce the 18 G needle into the stopper of the vial and slowly add all the sterile water for injection into the vial.
5. **Let the vial stand for at least 2 hours (do not shake during this period) to ensure that the powder is fully hydrated by the water. SCULPTRA®** can be stored at 2 to 8°C in the refrigerator or at room temperature up to 30°C during hydration (refer to Storage Conditions).
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 it is 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 needle to withdraw the appropriate amount of the suspension (typically 1 mL) into a single-use 1-3 mL sterile syringe. Do not store reconstituted product in the syringe.
8. Replace the 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.

CROMOFOTO S.r.l. GRAFICA - FOTOCOMPOSIZIONE
Via G. Tartini, 2 - 20158 - MILANO
Tel. 0123787 r.a. mail: cromofoto@tiscali.it
AZIENDA CERTIFICATA UNI EN ISO 9001:2008

89032021 (int. version 1)				20 GIU 2017	
TYPE OF MATERIAL: LEAFLET FOLDED	DESCRIPTION: SCULPTRA 150 MG		COUNTRY: AUSTRALIA	CAGE VERSION: A1	MIN. FONT SIZE: 8 pt.

CODE	VERSION	SOLO CODE	ORE CCIT.	DIMENSIONS mm:	COLOURS N°	COLOUR 1:
89032021 678104	1 a	89029935 625721	I021	125 x 420 (125 x 26,25)	1	REFLEX BLUE

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®**.
A complete medical history should be takem to make sure that the treatment is appropriate. 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. Universal precautions must be observed when there is a potential for contact with patient body fluids. The injection site should be cleaned with an antiseptic and free from contamination or infection.

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 **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 recheck for needle blockage.

4. The 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 the 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
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.
Volume per injection
The maximum volume of **SCULPTRA®** per each individual injection should be limited to approximately 0.1 mL – 0.2 mL spaced at a distance of 0.5 cm – 1 cm. Avoid overcorrection.
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 effects 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
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.
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 oedema 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 oedema 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). 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(s) to evenly distribute the product. 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 visualized with ultrasound imaging and MRI. If you are having an ultrasound or MRI performed on the area injected with **SCULPTRA®** inform your healthcare provider that you have **SCULPTRA®** injected in the area. **SCULPTRA®** is not observed with CT scans and X-rays.

10. Treat, wait, assess
During the first treatment session with **SCULPTRA®**, only a limited correction should be made. Do not overcorrect (overfill). The patient should then be evaluated at no sooner than four weeks post-treatment 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 informed of the potential need for additional treatments at the first consultation.

MODE OF ACTION
SCULPTRA® is implanted by subcutaneous or deep intradermal injections with a 26 G needle. The tight granulometric distribution of the microparticles of poly-L-lactic acid, its slow degradation kinetics, and a viscosity which is suitable for both deep intradermal or subcutaneous injections, gives **SCULPTRA®** its mechanical properties and prolonged resorbability, which make this implant suitable for filling areas of depressed skin.

STORAGE CONDITIONS
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 refrigeraton or at room temperature up to 30°C.
Do not freeze.
Do not use if package or vial is opened or damaged.
IF THE VIAL, SEAL OR THE FLIP-OFF CAP ARE DAMAGED, DO NOT USE, AND CONTACT GALDERMA (SEE CONTACT INFORMATION PROVIDED BELOW).
After patient use, treatment syringes and needles may be potential biohazards. Handle accordingly and discard the needles and syringes in a safe disposal container.

PATIENT INSTRUCTIONS
ANY SIDE EFFECTS OR PRODUCT COMPLAINTS SHOULD BE NOTIFIED TO GALDERMA (SEE CONTACT INFORMATION PROVIDED BELOW).

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

Sponsor
Galderma Australia Pty Ltd
Suite 4, 13B Narabang Way
Belrose NSW 2085
Phone 1800 800 765

New Zealand Distributor:
Healthcare Logistics
Phone 0800 174 104

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

Date of leaflet: November 2015

89032021
678104

CROM FOTO S.r.l. GRAFICA - FOTOCOMPOSIZIONE
Via G. Tartini, 2 - 20159 - MILANO
Tel. 02.373767 • e-mail: crom@cromfoto.com
AZIENDA CERTIFICATA UNI EN ISO 9001:2008

89032021 (int. version 1)

20 GIU 2017

TYPE OF MATERIAL	DESCRIPTION	COUNTRY	GRAD VERSION	MIN. FONT SIZE
LEAFLET FOLDED	SCULPTRA 150 MG	AUSTRALIA	A1	8 pt.

CODES	VERSION	SAP CODES	DIE CUT	DIMENSIONS mm	COLOURS N°	COLOUR 1
89032021 678104	1 a	89029935 625721	I021	125 x 420 (125 x 26,25)	1	REFLEX BLUE