SCULPTRA™
Poly-L-lactic acid
Sterile
1 vial

RECONSTITUTION
The following supplies are used with SCULPTRA and are to be used 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

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 sanofi-aventis Canada Inc. at 1-888-285-7872.
2. Attach 18 G sterile needle to a sterile single-use 5 mL syringe.
3. Draw 5 mL SWFI into the 5 mL 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 30°C during and after hydration. Refrigeration is not required.
6. After waiting at least 2 hours, agitate the vial until a uniform translucent suspension is obtained. A single drop size may be used. Product should be agitated immediately prior to use. The reconstituted product is usable within 72 hours of reconstitution. Following reconstitution discard any product after 72 hours.
7. Clean the penetrable stopper of the vial with an antiseptic, and use a new 18 G sterile needle to draw 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.

DEFINITION OF SCULPTRA
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.

HOW SUPPLIED
SCULPTRA is supplied as a sterile freeze-dried preparation 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.

COMPOSITION OF SCULPTRA
The vial contains: Poly-L-Lactic Acid, Sodium Carboxymethylcellulose, Nonpyrogenic Mannitol, Boric Acid, Sodium Hydroxide, Sodium Chloride, Water for Injection (SWFI).

INSTRUCTIONS 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, eye rings and for skin aging. SCULPTRA is also suitable for large volume corrections of the signs of facial fat loss (lipatrophies).

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 massaged using light pressure. Limited correction of the treatment area allows for the gradual improvement of the depressed area over several weeks prior to the achievement of the treatment effect. See "INSTRUCTIONS FOR USE" 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 attempt to correct (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, localized bleeding at the injection site. If this occurs, the needle should be removed and the treatment area gently massaged.

SIDE EFFECTS OF THE TREATMENT
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, transient edema or inflammation. Based on data obtained through post-marketing surveillance and clinical studies, nodules have also been reported. Subcutaneous nodules or visible nodules or areas of induration have been noted in the injection area and may be present at the site of needle insertion. These 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 the absence of any standardizing the treatment effect, patients should be informed that a certain degree of correction may also minimize the appearance of nodules. Other rarely reported adverse events include abscess, local infection, late granuloma formation, allergic reaction, skin hypertrophy, and atrophy. These events can occur in nodular areas or late granuloma formation, the treatment may include multiple intralesional injections of corticosteroids or other such agents or elective excision.

ANY SIDE EFFECTS OR PRODUCT COMPLAINTS SHOULD BE NOTIFIED TO THE CORRESPONDING ADDRESS: sanofi-aventis Canada Inc., 2150 St.Edward Blvd. West. Laval, Quebec, Canada H7L 4B8
1-888-285-7872

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. Refrigeration is not required. Do not freeze.

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

INSTRUCTIONS FOR USE
1. Patient Assessment. Before treatment with SCULPTRA, the patient should be informed completely of the indications, contraindications, warnings, precautions for use, possible side effects and modes of treatment of SCULPTRA. A complete medical history should be taken to determine if the treatment is appropriate. Patients should be informed that more than one injection session is typically necessary to achieve the desired results.
2. Patient Preparation. 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. Agitate the product in the syringe as needed to maintain a uniform suspension throughout the procedure. Before injecting, expect some particles of the product from the tube to be aspirated into the syringe to avoid air entrainment and to check for needle blockage. If the 26 G needle becomes occluded or dull during an injection session replacement may be necessary. Draw a small amount of air into the syringe before inserting the needle. The patient should be instructed to avoid using needle changes to assist in clinical technique.
4. The deep dermal plane. SCULPTRA should be injected into the deep dermis or subcutaneous layer to control to the direction of the injection to create a firm 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 evident when the needle traverses the dermal-subcutaneous junction. If the needle is inserted at too shallow an angle [i.e., into the mid or superficial (palpillary) dermis] the needle of the needle may be visible through the skin. If product is injected too superficially it will be evident as immediate or slightly delayed blanching of the injected area. If this occurs, the needle should be removed and the treatment area gently massaged.
5. Injection: Threading or Tunneling
a. In general, 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 reflex 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 volume of SCULPTRA should be limited to approximately 0.1 mL – 0.2 mL per individual injection.
   c. Volume per treatment area. The volume of product injected per treatment area will vary depending on the surface area to be treated. Multiple injections (typically administered in a grid or cross-hatched pattern) may be required to cover the targeted area. 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. Injection: Depot
a. The depot technique is most appropriate for injections into areas of thin skin at the level of the upper zygoma or temples. When using this technique, SCULPTRA is injected as a small bolus. For the upper zygoma it is injected under the orbicularis oculi muscle. For the temples, it is injected in the temporal fascia.
   b. Volume per injection. The volume of SCULPTRA should be reduced to approximately 0.05 mL/ injection. Following each injection, treat, wait and assess.
7. Massage during the injection session. The treatment areas should be periodically massaged during the injection session to evenly distribute the product.
8. Begining of correction. The deposit of correction 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 a new degree of edema associated with the 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 delancing in the injected area. If this occurs, the needle should be removed and the treatment area gently massaged.
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 SIDE EFFECTS OF THE TREATMENT for additional details. The patient should be instructed to gently massage the area for several weeks to determine if additional correction is needed. The original skin edema may initially reappear following the injection session improvement and should gradually improve in a few days to 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.

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