PRP SCIENCE

Olidia®

INJECTABLE POLY-L-LACTIC ACID POWDER

【Product Name】

Sterile Absorbable Poly-L-Lactic acid (PLLA) Dermal Filler

【Brand Name】 Olidia

【Model Name】 Olidia

【Intended Use】

It is used as injection using syringe into deep dermis for the treatment of severe facial wrinkles and folds, replacement of volume defects, facial lipoatrophy and improvement of facial contour deformities.

【Indication】

For treatment of severe facial wrinkles and folds, replacement of volume defects, facial lipoatrophy and improvement of facial contour deformities.

【Composition of Olidia】

Each vial of dry powder contains:
150mg of Poly-L-lactic acid
90mg of Sodium Carboxymethylcellulose
125mg of Mannitol

A. Preparation before Use

- Make sure to check whether the product packaging is damaged or broken.
- Check for any deformation of the product's appearance or for any foreign materials attached to the product.
- Before using the product, doctors should fully familiarize themselves with this instruction guide.
- Reconstitution procedures of the product should be aseptically conducted in an environment free from microorganism contamination.

1. After removing the cap of the vial, wipe its rubber stopper with an antiseptic. If the aluminum cap or rubber stopper of the vial is damaged, do not use the product.
2. Connect an 18 G sterile needle to a 5ml sterile, single-use syringe as shown in the table below and slowly add the sterile WFI (Water for Injection) into the vial.

Model Name	PLLA compound Amount	WFI(Water for Injection) (ml)
Olidia	365mg(1Vial)	5ml

3. Let the vial stand for at least 3 hours to ensure complete hydration; do not shake during this period.
4. Product should be gently agitated directly prior to use. Agitate the vial until a uniform translucent suspension is obtained. For this agitating process, 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.
5. Shake the reconstituted solution directly prior to treatment in order to produce a better suspension.
6. Each time a patient is treated, wipe the rubber stopper of the vial with an antiseptic and use an 18 G sterile needle connected to a 1 or 3 ml disposable sterile syringe, to withdraw an adequate amount of suspension from the vial.
7. At the time of treatment, use a 26 G sterile cannula needle or a 26 G sterile needle depending on the case-by-case treatment purpose.

B. How to Use

The treatment with the product should be performed using the Linear Threading Technique.

1. Before injection, explain clearly the indications and cautions (e.g. prohibitions, warnings, general care, potential side effects or adverse events), and injection methods associated with the product to the patients. Before treatment, doctors should thoroughly examine the medical history of the patients to be treated and make sure that the injection of the product is appropriate for the concerning patients.
2. Explain to the patients that the injection amount and frequencies may vary depending on the circumstance and the degree of wrinkles and folds of individual patients.
3. Like all the other transdermal therapies, patients may be exposed to the risk of infection by the injection of the product. Doctors must abide by general sterilization and sanitation rules. If there is a possibility of contact with the body fluids of patients, precautionary measures should be taken. Make sure to clean the injection site with an antiseptic.
4. During the injection treatment, periodically massage the injection site to evenly distribute the product.
5. In order to adjust the injection depth and create a firm injection surface, stretch the skin in the opposite direction of the injection. The needle, bevel up, should be introduced into the skin at an angle of approximately 30-40 degrees, until the desired skin depth is reached.
6. When the syringe needle penetrates the dermal-epidermal junction (DEJ), some change in tissue resistance must be felt. If the needle is inserted at an angle that is too shallow (in case of being inserted into the middle or the surface of the papillary dermis), the needle bevel can be seen through the skin.
7. If the reconstituted solution injection is too shallow, the injected area will blanch slightly, immediately after injection. If this occurs, remove the injection needle and gently massage the injection site.
8. If the blanching does not disappear, the patient should not be re-injected.
9. In general, patients may experience some degree of swelling because of the injection treatment itself. Because of this swelling, the injection site may appear to be entirely mended (within 30 minutes) shortly after injections.
10. Patients should be informed that the swelling will be resolved within several hours to a few days after injection, resulting in the reappearance of the original contour deficiency.
11. After injection, redness, swelling and/or bruising may occur. In this case, wrap ice cubes or an ice pack with fabric (avoiding any direct contact of the ice with the skin) and apply the ice pack to the treatment area to reduce swelling or bruising caused by the injection.
12. After the syringe treatment, patients should massage the treated area for five minutes, five times a day, to promote a natural-looking correction.
13. At the initial stage of injections, the original folds or wrinkles may re-appear, but they will soon disappear as the injection takes effect. Notify the patients of the possibility that additional injection treatment may be necessary after the initial treatment.
14. In the case of injection treatment, only moderate corrections should be made using the product. Any excessive corrections or injections should be prohibited.

C. Storage and Maintenance after Use

- Do not reuse or re-sterilize the product.
- Since each vial of the product is loaded for single-use only, it is strictly prohibited to reuse the product once the sealed package is opened or the product is used.
- The waste should be discarded in the designated collection bins or containers.
- The product is susceptible to high temperature.
- Do not store in environments over 30℃.
- Do not refrigerate the product.
- Avoid strong impact or collision during product handling to prevent any damage.

D. Warnings

1. The product should be injected only into the lower layers of the dermis or the layers of the hypodermis.
2. Like other injections, in cases of the patients who have been administered anticoagulants, the product may carry the risk of haematoma or local bleeding in the injection site.
3. Do not inject the product at a shallow depth, closer to the outer layer of the skin, in order to prevent early papules or nodules at the injection site.
4. If the product is injected into blood vessels, it may obstruct the blood vessels or their flow, and cause skin embolism.
5. In order to avoid contamination, each vial package must be used for one single patient only. Since the product is a disposable single-use material, do not re-use or re-sterilize after opening its seal or reconstituting the solution.
6. If the sealed package is broken, damaged or modified, do not use the product.
7. It is strictly prohibited to use the product for other purposes except its originally intended purpose.
8. Before treatment, make sure that the prepared product has completed the reconstitution as it is indicated in the preparation guideline of the product.
9. A sterile, disposable 26G needle or cannula must be used for this injection treatment.

E. Contraindications

1. Do not inject the product into patients with acute or chronic skin diseases (infection or inflammation) either at the injection site or surrounding areas.
2. Do not inject the product into patients who are highly sensitive to the product and its components.
3. The safety of using the product on patients with susceptibility to excessive scarring (keloids) has not been established.
4. If the product is injected into patients who have a history of herpetic eruption, then herpetiformis may recur.
5. Do not inject the product into patients with malfunction of the liver or blood coagulation.

F. Potential Adverse Events

1. Reaction at the injection site
   - Hemorrhage
   - Pain
   - Induration
   - Swelling
   - Tenderness
   - Lesion
   - Bleeding
   - Fever
2. Abnormality in the immune system
   - Hypersensitive Angioedema
   - Skin sarcoidosis
   - Dermatitis
   - Severe allergic reactions including heart palpitations, hives, keloids and systemic auto-immune

reaction
3. Inflammation and infection
  - Infection of the injection site including facial cellulitis
  - Bacterial infection
  - Abscess at the injection site
4. Abnormality in skin and subcutaneous tissue
- Bruising
- Hematoma
- Atrophy or skin hypertrophy at the injection site
- Erythema at the injection site
- Urticaria at the injection site
- Telangiectasis
- Most papules in the subcutaneous tissue can be sensed by palpation, but they are not visible, and have no symptoms.
- After treatment, modules including periorbital ones may be accompanied with inflammation or discoloration. Subcutaneous nodules detected at the initial stage of injection can be minimized with adequate dilution and injection.
- Subcutaneous nodules may be apparent later (within 1 to 14 months after injection), and may last up to two years.
- It may be necessary to remove nodules voluntarily, surgically, or with the treatment of intralesional corticosteroids.
- Granuloma
- Scarring
- Skin discoloration
5. Etc.
- Discomfort
- Ecchymosis
- Photosensitive reaction
- Fatigue
- Hair breakage
- Brittle nails
- Application site discharge
- Aching joints
- Telangiectasias

G. General Precautions

1. The treatment with the product should be done by a specialist doctor who has completed mandatory training.
2. Before injecting the product, clearly explain to the patients the indications of the product, prohibitions, and potential side effects.
3. Before using the product, make sure the sterile condition is not compensated or contaminated.
4. Check the expiration date on the product label.
5. The injection site should be cleaned with antiseptic gauze and there should be no inflammation or infection.
6. After injection, the patients should be notified that they should take greater care of the injection sites, with extra caution regarding aspects of age, gender or health conditions in consideration of particular features of medical devices or products.
7. Since the effect of the treatment gradually appears within several weeks after injection, do not overcorrect (overfill).
8. Do not use the product until the inflammation or infection, if any, is controlled.
9. The safety and effectiveness of the product for lip augmentation has not been established.
10. This product must be used after being compounded with sterile water for injection.
11. The long-term safety and effectiveness of the product other than the periods indicated in relevant clinical studies have not been evaluated or established.

H. Interaction

No research has been done on the interaction of the product with other drugs, components, and implants.

I. Cautions for pregnant women, breast-feeding mothers, newborn babies, infants, children or the elderly

The safety of using the product during pregnancy, in breastfeeding mothers or in patients under the age of 18 has not been evaluated or established.

J. Cautions during Treatment

1. When the product is injected into blood vessels, serious adverse effects including the loss of eyesight may occur. It is strongly recommended not to use the product in the periorbital areas including the areas between the eyes where the skin is thin and where it is highly likely to be injected into blood vessels. Extra care should be taken during the treatment.
2. Be aware of the reported risks of increase in papules or nodules due to injection into thin skin, overfilling and incorrect compounding of the solution. The occurrence of papules or nodules can be minimized by massaging the injection site to evenly distribute the injected product.
3. Do not inject into the vermilion areas of the lips.
4. Avoid injection into blood vessels which may cause vessel occlusion and subsequent tissue necrosis.
5. This product is visible through ultrasonic imaging and MRI but is not visible through CT scans or radiography.

【Storage】

Store at room temperature below 30℃. Do not freeze.

【Shelf-life & Expiration Date】

21 months from the date of manufacture.

【Packing Unit】

1 Vial/Box

【Disposal condition】

Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

[Description of the symbol on the label]

No.	Symbol	Description
1		Symbol for “Manufacturer”
2		Symbol for “Authorized Representative in the EC”
3		Symbol for “Catalogue number”
4		Symbol for “Lot number”
5		Symbol for “Expiration date”
6		Symbol for “Sterilized using Irradiation”
7		Symbol for “Do not reuse”
8		Symbol for “Do not re-sterilize”
9		Symbol for “Date of Manufacture”
10		Symbol for “Consult instruction for use”
11		Symbol for “Keep away from sunlight”
12		Symbol for “Temperature limitation”
13		Symbol for “Do not use if package is damaged”
14		Symbol for “CE marking” approved by PCBC (NB No. 1434)
15		Symbol for “Fragile”
16		Symbol for “Handled with care”
17		Symbol for “Right way up”
18		Symbol for “Keep Dry”
19		Symbol for “Medical Device”

Contact the PRP SCIENCE Co., Ltd. for additional information, to place an order, or to report adverse reaction.

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