

LA-2501

Instructions for Use (IFU)

[Product Name] PiNkLLA (PLLA + PN + HA + Vitamin C + Glutathione)

[Brand Name] LA-2501

[Packaging Unit] 1 vial of lyophilized powder

[Intended Use]

LA-2501® is intended for dermal injection (mid-to-deep dermis) or MTS-assisted topical delivery by trained professionals to stimulate collagen regeneration, improve pigmentation, hydration, and skin elasticity.

[Indications]

LA-2501® is indicated for the aesthetic treatment of fine wrinkles, pigmentation, acne scars, large pores, and skin laxity, improving overall texture and elasticity in areas such as the face, neck, décolletage, and hands.

[Composition]

Each vial of LA-2501® contains sterile lyophilized dry powder in a ball-type particle format with the following composition:

Poly-L-Lactic Acid (PLLA): 35 mg

Polynucleotide (PN): 8 mg

Sodium Hyaluronate (HA): 9 mg

[Contraindications]

1. Known hypersensitivity to any component of the formulation, including Poly-L-Lactic Acid (PLLA), Polynucleotide (PN), Sodium Hyaluronate (HA), Vitamin C, Glutathione, or excipients (e.g., lidocaine).
2. Active skin infections, inflammation, or open lesions at or near the injection site (e.g., herpes simplex, acne, eczema, dermatitis, or open wounds).
3. History of severe allergic reactions or anaphylaxis.
4. Pregnancy or breastfeeding, due to insufficient safety data.
5. Known bleeding disorders or ongoing anticoagulant/antiplatelet therapy.
6. Autoimmune or immunosuppressive conditions (e.g., lupus, sarcoidosis); use only with physician judgment.
7. History of keloid formation or hypertrophic scarring.
8. Age under 18 years, unless approved for pediatric use.

9. Prior treatment in the target area with non-absorbable fillers (e.g., silicone-based implants).

[Warnings & Precautions]

1. LA-2501® must only be administered by trained medical professionals using proper injection or microneedling techniques.
2. For injections, incorrect placement depth may increase the risk of nodules, papules, or uneven distribution.
3. Avoid intravascular injection. Inadvertent vascular administration may result in embolism, tissue necrosis, or other severe complications.
4. Patients on anticoagulant or antiplatelet therapy may have an increased risk of bleeding or hematoma. Use with caution.
5. Each vial is for single-patient use only. Do not reuse or re-sterilize after opening or reconstitution.
6. Do not use if the vial seal is broken or the packaging is damaged or tampered.
7. Always maintain aseptic technique. Use only sterile, disposable needles or microneedling devices.
8. Avoid injection into high-risk anatomical zones such as the glabella, nasal dorsum and tip, tear trough, or vermilion border, due to higher risk of complications.
9. For topical/MTS use, do not apply to inflamed, infected, or broken skin.
10. Do not combine treatment in the same session with potentially irritating topical agents (e.g., retinoids, AHAs, BHAs, high-concentration vitamin C serums).
11. LA-2501® is strictly intended for the indications described in this IFU. Do not use for any other purposes.

[Storage]

Store at room temperature below 30°C, in a dry place away from direct sunlight and moisture. Do not freeze.

[Disposal]

Dispose of all components in accordance with: accepted medical practice, applicable national and local regulations and institutional guidelines for biohazard and sharps disposal.

[Reconstitution Procedure]

1. Required Materials:
One vial of LA-2501®, 6 mL of sterile water for injection or sterile saline (0.9% NaCl), 18G or larger mixing needle, sterile 10 mL syringe, and 27G/25G injection needle. Ensure all components are sterile and at room temperature. Use aseptic technique throughout the procedure.
2. Preparation:
Using a sterile 10 mL syringe, draw up 6 mL of sterile water for injection or sterile saline (0.9% NaCl).

3. Reconstitution:
Slowly inject the diluent into the LA-2501® vial along the inner wall.
4. Mixing:
Shake the vial by hand for approximately 1-2 minutes until the contents are completely dissolved and a uniform suspension is obtained.
5. Hydration:
Allow the vial to stand undisturbed for 2 minutes to ensure complete hydration of PLLA and uniform dispersion of components.
6. Withdrawal & Use:
Use a sterile syringe to withdraw the required volume of the reconstituted product for immediate use. The mixture should be used within 8 hours after reconstitution. If not used immediately, store under refrigeration (2–8°C) and discard any unused product after 8 hours

[Treatment Protocol]

A. Topical / MTS Protocol

1. Treatment must be performed by licensed professionals with appropriate training in skin procedures and device-assisted delivery.
2. Apply topical anesthetic cream to the treatment area 20–30 minutes before microneedling (when needle depth >0.5 mm).
3. After antiseptic cleansing, apply reconstituted LA-2501® to the treatment area.
4. Use a microneedling device (Dermapen, MTS roller) to deliver LA-2501® into the skin, reapplying solution as needed throughout the procedure.
5. Recommended Needle Depths (MTS / Dermapen):
0.25–0.5 mm: Pigmentation, skin brightening, superficial tone
0.5–1.0 mm: Fine wrinkles, enlarged pores, texture
1.0–1.5 mm: Wrinkles, acne scars, skin laxity
≥ 1.5 mm: Deep scars (doctor's discretion only)
6. After treatment, apply a final thin layer of LA-2501® and leave for 2–3 minutes to support absorption.
7. Do not rinse the treated area for at least 4–6 hours after application to allow optimal absorption.
8. If there is pinpoint bleeding, gently dab with sterile gauze to remove blood, without wiping away the applied product.
9. Complete the procedure by applying a soothing or regenerative cream/gel.
10. Treatment schedule: Initial 3–4 sessions at 2–3 week intervals, followed by maintenance every 2–3 months.

B. Injection Protocol

1. Treatment must be performed by licensed medical professionals with proper training in injection techniques and facial anatomy.
2. Apply topical anesthetic cream to the treatment area 20–30 minutes before injection.

3. After antiseptic cleansing, reconstituted LA-2501® should be loaded into a sterile syringe.
4. Use a 27G needle (recommended) or 25G needle (optional) for serial puncture injections into the mid to deep dermis.
5. Injection method: Serial puncture with micro-depots (≤ 0.05 mL per point), spaced 0.5–2 cm apart, to ensure uniform dermal distribution.
6. Target planes by area:
Cheeks / mid-face: mid to deep dermis with serial puncture.
Forehead: mid dermis using very small aliquots (≤ 0.02 mL) with closely spaced serial puncture.
Neck: mid dermis with serial puncture in evenly spaced points.
7. Do not inject LA-2501® into the glabella, nasal dorsum, or nasal tip, as these areas carry a high risk of vascular compromise. In addition, avoid placement in the superficial dermis to reduce the risk of visible nodules or Tyndall effect.
8. Injection in the tear trough, perioral region, and temple should only be performed by experienced practitioners using a 25-27G blunt cannula. These areas are anatomically high-risk due to dense vascular structures and thin tissue planes, and require advanced knowledge of facial anatomy.
9. Total treatment volume: adjust according to patient's indication and facial size; avoid exceeding safe tissue capacity.
10. Treatment schedule: 3 sessions spaced ~4 weeks apart, followed by maintenance every 6–12 months depending on clinical judgment.
11. When combining with energy-based devices (e.g., RF, HIFU, LIUS), perform device treatment first, followed by LA-2501® injection to minimize disruption of PLLA distribution and optimize regenerative effects. Energy settings are generally unchanged; consider slight reduction in sensitive areas.
12. Complete the procedure by applying a soothing or regenerative cream/gel.

[Post-Treatment]

Patients should avoid strenuous exercise, alcohol consumption, and heat exposure (including sauna, hot baths, or intense physical activity) for at least 24–48 hours, with some practitioners advising up to 72 hours to optimize safety and PLLA integration. Application of soothing or regenerative cream/gel is recommended to support recovery.