Polynucleotide Filler with Lidocaine

MONALISA PN

Instruction for Use

Product name: MONALISA PN
Polynucleotides Dermal Filler

Description

MONALISA PN is the sterile, transparent gel of stabilized polynucleotides with 0.3% lidocaine. MONALISA PN is supplied in a glass syringe with a Luer-lock fitting. The contents of the syringe have been sterilized using moist heat and pressure. The product is for single use only. Disposable sterile needles are provided with the syringe.

Composition

- Stabilized polynucleotides gel 20mg/mL
- Lidocaine HCl ..... 3 mg/mL
- Phosphate Buffered Saline ..... q.s.

Intended Use

MONALISA PN is intended for soft tissue augmentation and restoration of facial lipoatrophy, which contains the local anesthetic lidocaine for a more comfortable injection in patients over 18.

Indication for Use

1. Precaution Before Use

- Use the product after examining the packaging for damage or contamination of the product and checking the expiration date. Do not use expired, damaged, or contaminated products.
- Before use, the application of this product must be suitable for the patient, and the patient's medical history must be checked.
- Before use, the physician must be informed of the purpose, expected results, precautions, and possible adverse events to the patient.
- Allow the product to room temperature before injection.
- Only to be administered by appropriately trained physician who are qualified or accredited in accordance with national law.

2. Procedures of Use

- Open the package containing the syringe.
- Using sterile needles and cannula, approved medical devices matching the Luer-lock specifications of syringes, is essential for safe handling.
- To prevent the sealing of the product from being released or the product from escaping due to the viscoelasticity of the product, hold the Luer-lock device with one hand and twist the cap in the opposite direction with the other hand to remove the cap.
- Pull out the needle's protection cap horizontally.
- Hold the junction of the syringe's Luer-lock with one hand and the sterile needle with the other. Rotate the needle into the syringe to securely fix it.
- The needle must be correctly attached to the syringe for safe handling. Incorrect attachment can result in the detachment of the syringe and the needle.
- Do not bend the needle to prevent breakage.
- The target area must be disinfected with the aseptic solution.
- To remove air from the interior of the syringe, slowly press the rod until a droplet forms at the tip of the needle.
- If the needle does not go in well, do not forcefully push it in, but pull it out and try to another area.
- The physician slowly injects the injection solution into the area where the procedure is needed using an appropriate injection technique.
- The amount of injection is appropriately judged and applied by the physician according to the condition of the application area.
- Stop injection if the injected area becomes pale, and massage the injected area until the color returns to normal.
- Stop injection before completely pulling out the needle.
- Use a new needle and cannula for each injection site.
- After injection, gently massage the treated area to distribute it well into the surrounding tissue, and if there is swelling, remove that with an ice pack.
- The periodic additional injection helps to achieve desired results. The injection can be adjusted depending on the user's discretion and the patient's preference.

3. Storage Following Use

- After the procedure, dispose of used products, including needles and cannulas, as medical waste.
- This product is a single-use medical device, and the reuse of remaining products is prohibited due to the possible risk of contamination, deformation, and infection.

Precautions During Use

1. Contraindication

- The product is to be used only for intradermal injections.
- This product is not injected into blood vessels. Unintended introduction into blood vessels could cause blindness, occlusion, ischemia, tissue necrosis, stroke, etc.
- The product not be used on patients with allergic disease, autoimmune disease, sarcoid granulomatous disease, or endocarditis.
- The product not be used on patients with bleeding disorders or those taking thrombolytic agents, aggregation inhibitors, NSAIDs, anticoagulants, immunosuppressants, etc.
- It should not be used in patients with hypersensitivity to components of this product (sodium polynucleotide, lidocaine) or anesthetic of the amide type.

2. Precautions Regarding Age, Sex, and Physical Conditions

- Do not inject the product into an area where another manufacturer's product is present.
- Do not inject the product into areas where non-injectable implants are already present.
- Safety & Effectiveness for Lip Augmentation are not established.
- Do not use this product on pregnant, breastfeeding women or children (under the age of 18).

3. Precautions for Undesirable Effects

- Do not inject excessive amounts or too shallow which can result in the temporary formation of a lump.
- Physicians must inform patients of potential or acute side effects related to this product use.
- Common injection-related reactions such as erythema, swelling, pain, itching, bruising, or tenderness may occur after injection of this product. These reactions gradually fade over time.
- These include:
  Frequency of 1/10,000 ~ 20,000: Edema, bruising, erythema, light pain, tenderness.
  Frequency of 1/50,000: Infection, inflammation, blanching, papules, nodules.
  Low frequency of the following: itching, hypersensitivity, reactivation of latent for subclinical herpes infection, acne, granuloma, blistering, clotting, facial edema, rash, dermatitis, scarring, skin atro atrophy, reduction of duration time, ischemia, tissue damage, and augmentation of the capillary.
  Cases of visual impairment from unintended injections into facial veins have been reported.
  Cases of inflammation accompanying red spots, edema, tenderness, clotting, and other symptoms have been reported.
  Cases of pigmentation after inflammations due to melanin accumulation have been reported.
- Safety for a patient being sensitive to keloid pathogenesis, hyperpigmentation, and the hypertrophic scar is not established.
- The infection site should be treated adequately, or implanted filler should be removed. If the symptom is severe, corticosteroid treatment could be effective.
- The decision of re-injection for patients who experienced any clinically significant reactions should be made after considering the cause and seriousness.
- Safety & effectiveness for long-time use are not established except for a period verified through a clinical test.
- Inflammation (redness, swelling, erythema) may occur along with itching or pain when pressure is applied to the injection site. These reactions may last for up to a week.
- The nodules or hardening at the injection site, discoloration at the injection site, and lack of therapeutic effect may occur after injection.
- Instruct patients to seek medical attention as soon as possible if inflammation persists for more than a week or if other side effects other than those known occur. Physicians should administer appropriatetreatment.
- Any side effects should be notified to the physician or the manufacturer

4. Other Precautions

- Avoid makeup for 12 hours after injection and avoid prolonged exposure to the sun, UV rays, cold, or heat (sauna, steam room, etc.) for 2 weeks.
- Following injection, the patient should minimize exposure to excessive sunlight or cold until the initial edema and erythema become less severe.
- After the injection with this product, if treated with laser treatment, chemical peels, or other treatments based on active skin reactions before the complete recovery, may occur an inflammation reaction at the transplant site. Also, Inflammation may occur if this product is implanted after these other treatments and before the skin has recovered.
- Keep out of children.
- Any injections include the risk of infection. Aseptic environments and standard procedures must be followed to prevent cross-contamination.
- It is not appropriate to inject in patients with unattainable expectations.
- Do not use it if the product is expired or the package is opened or damaged.
- The expiration date applies only to products under appropriate storage conditions.
- Do not administer if impurities are identified in the injection.
- It is recommended that the amount of product used in each operation site per procedure to be less than or equal to 2mL.

5. Biological Interactions

- Extreme precaution is needed when operating near weak tissues such as nerves and veins, or any permanent implants.
- Do not use the product when inflammation, infection, tumor, or active form of other disease is near the intended injection site.
- The injection can reactivate any latent or subclinical herpes virus infection.
- Patients using substances that affect platelet function, such as aspirin and non-steroidal anti-inflammatory drugs, may experience increased bruising or bleeding at the injection site, as with other injections.

6. Use for Pregnant Women, Lactating Women, Women of Childbearing Potential, Newborns, Infants, Children, and The Elderly

- Do not use in pregnant or lactating women or children.

7. Precaution for Application

- Do not combine with other products.
- Do not re-sterilize.
- It should be used immediately after opening.
- The amount of product used for each target area is recommended to be 2mL or less.

8. Safety Information

- Do not use the product until infection or inflammation is controlled.
- In the case of patients with dermatitis herpetiformis, the injection of the product may cause the recurrence of this disease.
- The following adverse reactions have been reported with lidocaine injection.
  1) Shock: Shock may occur, so observe closely. If blood pressure drop, facial pallor, pulse abnormality, respiratory depression, etc. occur, the injection is immediately discontinued, and appropriate measures are taken.
  2) Malignant hyperthermia: Rarely, severe malignant hyperthermia occurs and may be accompanied by unknown causes, tachycardia, arrhythmia, blood pressure fluctuation, rapid increase in body temperature, muscle rigidity, dark red blood (cyanosis), hyperventilation, sweating, acidosis, hyperkalemia, myoglobinuria (red urine), etc. If these symptoms, accompanying malignant hyperthermia, appear during treatment of this drug, immediately stop treatment and take appropriate measures such as intravenous injection of dantrolene sodium, systemic cooling, hyperventilation by pure oxygen, and correction of acid-base equilibrium, etc. In addition, since this symptom can lead to renal failure, it is necessary to maintain the urinary flow.
  3) Central nervous system
     - It may occur intoxication symptoms, such as tremors and convulsions, so thoroughly observe. If these symptoms appear, immediately stop administration and take appropriate measures such as administration of diazepam or ultrashort-acting barbiturate (thiopental sodium).
     - Drowsiness, anxiety, excitement, ignoring, dizziness, vomiting, nausea, etc. may occur, so observe thoroughly, pay attention to the transition to shock or poisoning symptoms, and take appropriate measures as necessary.
  4) Hypersensitivity: breathing difficulties due to bronchoconstriction, edema, and skin symptoms, such as hives, etc., may occur.

9. Absorbable Information

- MONALISA PN is a bio-absorbable gel in which gradually absorbed into the body. As the gel breaks down, water takes its place, and when completely absorbed, the gel disappears unnoticed frof from the body.
- Duration is individual. This depends on many factors, such as the patient's age, skin type, lifestyle, muscle activity, and physician's injection technique.
- Absorbable injectable dermal fillers can occur delayed side effects such as inflammation, erythema, or swelling.

Mass/Packing Unit

Refer to the product label.

Storage

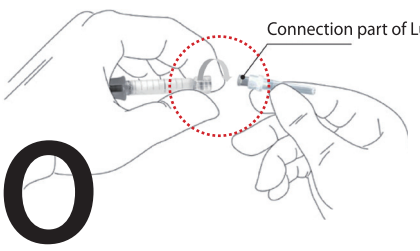
- Store at room temperature(2~25°C)
- Protect from sunlight
- Do not freeze the product

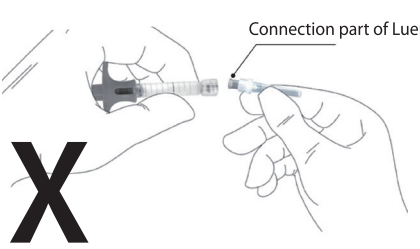
Expiration Date

Refer to the product label.

Symbols

REF	Catalogue number	LOT	Batch code
	Do not reuse		Caution
	Date of manufacture		Use by
	Manufacturer		Do not resterilize
	Temperature limitation		Keep away from sunlight
	Fragile, handle with care		Do not use if package is damaged
STERILE	Sterilized using steam	BIO	Contains biological material of animal origin
	Single sterile barrier system with protective packaging outside		Contains a medicinal substance
	Consult instructions for use	MD	Medical device
UDI	Unique device identifier		





Hold the junction of the syringe and the Luer-lock with one hand and the sterile needle shield with the other. Rotate the needle to securely fix it to the syringe.

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