MONALISA Resilience PN

English

Polynucleotides Intra-Articular Injection with Lidocaine

A Device Generic Name

Sterile Intra-articular Injection

B Description

MONALISA Resilience PN is a transparent gel of stabilized polynucleotides with 0.3% lidocaine. MONALISA Resilience 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.

C Composition

- Stabilized polynucleotides gel ····· 20mg/mL
- Lidocaine HCl ····· 3 mg/mL
- Phosphate buffered saline ····· q.s.
- Each syringe contains 2mL of MONALISA Resilience PN.

D Intended Use

MONALISA Resilience PN is injected intra-articular of the knee and used to reduce mechanical friction in the articular area through physical restoration.

E 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 treatment, the application of this product must be suitable for the patient, and the patient's medical history must be checked.
   - Before treatment, the physician must be informed of the purpose, expected results, precautions, and possible adverse events to the patient.
   - Allow product to come to room temperature before injection.
   - Only to be administered by appropriately trained physician who are qualified or accredited in accordance with national law.
2. Treatment Procedures
   - 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.
   - Hold the junction of the syringe and the Luer-lock with one hand and the sterile needle shield with the other. Rotate the needle into the syringe to securely fix it.
   - After attaching the needle to the syringe, pull out the needle protection cap horizontally.
   - 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 treatment 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 before completely pulling out the needle.
   - Use a new needle and cannula for each injection site.
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.

F Precautions During Use

1. Contraindication
   - It should not be used in patients with hypersensitivity to the components of this product (sodium polynucleotide, lidocaine) or anesthetic of the amide type.
   - Do not inject outside the joint cavity, intravascularly, synovial tissue, or joint membrane.
   - If intra-articular exudation, remove the exudate by suction before injection.
   - Avoid physical exercise excessively on the knee within 48 hours after intra-articular injection.
   - Do not use quaternary ammonium and chlorhexidine disinfectants.
   - The product not be used on patients with bleeding disorders or those taking thrombolytic agents or anticoagulants.
2. Precautions Regarding Age, Sex, and Physical Conditions
   - To prevent the possibility of developing bacterial arthritis, do not use it when there is inflammation due to infection or when there is an infection near the affected area.
   - Special care is required when administering to patients with lymphatic or venous congestion.
   - Efficacy and safety have not been established for pregnant or breastfeeding women and children.
   - Lidocaine may cause local seizures or hypersensitivity reactions, and skin symptoms such as hives and edema may appear.
3. Precautions for Undesirable Effects
   - Physicians must inform patients of potential or acute side effects related to this product use.
   - Erythema, redness, swelling, pain, itching, bruising, or tenderness may occur after injection.
   - The above symptoms can be relieved by resting the joint and applying cold compresses, and most of them disappear quickly. If symptoms persist, see a physician.
   - Any side effects should be notified to the physician or the manufacturer.
   - Shock may occur when the lidocaine is injected, so observe closely. If occur blood pressure drops, facial pallor, pulse abnormalities, respiratory depression, etc., the injection is immediately discontinued, and appropriate measures are taken.
4. Other Precautions
   - Keep out of children.
   - Any injections include the risk of infection. Aseptic environments and standard procedures must be followed to prevent cross-contamination.
   - 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.
5. Biological Interactions
   - Quaternary ammonium preparations and chlorhexidine preparation disinfectants cannot be used as preoperative disinfectants.
   - Do not use the product when inflammation, infection, tumor, or any other active form of disease near the intended injection site.
   - 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.
8. Safety Information
   - Avoid using the product on blood vessels, considering the possibility of causing occlusion, tissue necrosis, etc.
   - Do not use the product until infection or inflammation is controlled.
   - 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.
     1) Hypersensitivity: breathing difficulties due to bronchoconstriction, edema, and skin symptoms, such as hives, etc., may occur.
9. Absorbable information
   - MONALISA Resilience 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 from the body.
   - Duration is individual. This depends on many factors, such as the patient's age, lifestyle, muscle activity, and physician's injection technique.

G Mass / Packing Unit

Refer to the product label.

H Storage

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

I Expiration Date

Refer to the product label.

GENOSS

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Symbols

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

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