MONALISA SKIN

A Device Generic Name

Injectable Dermal Filler

B Description

MONALISA SKIN is a sterile, transparent gel of stabilized hyaluronic acid of non-15 animal origin. MONALISA SKIN is supplied in a glass syringe with a luer-lock fitting. The Contents of the syringe have been sterilized using moist heat(122℃, min). The product is for single use only. Disposable sterile needles are pro-vided with syringe. Information about size of the needle is printed on its packaging.

C Intended Use

MONALISA SKIN is intended to be used for temporary improvement of facial wrinkles.

D Indication for use

1. Precautions 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.
   - The patient must be informed of the purpose, expected results, precautions, and possible adverse events before treatment.
   - Proper injection technique is essential to obtain favorable results. Injection technique of the manufacturer prior to initial injection is important for a more successful injection.
   - Only qualified medical professionals must administer the treatment.
2. Treatment Procedure
   - The use of sterile needles and cannula matching the Luer-lock specifications of the syringe is essential for safe handling.
   - 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. 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.
   - The treatment area is to be disinfected with aseptic solution.
   - Do not bend the needle to prevent breakage.
   - The product should be injected into the dermis or the lower part of the dermis.
   - To remove air from the interior of the syringe, press the rod slowly until there is a small drop at the tip of the needle.
   - Aspiration before use is recommended when using a needle. Inject content while slowly pulling the needle backwards.
   - Stop injection before fully pulling out the needle.
   - Use a new needle and cannula for each injection site.
   - Massage the injection site following injection to facilitate conformation to surrounding tissue.
   - Periodic additional treatment helps to achieve desired results. The treatment can be adjusted depending on the user's discretion and the preference of the patient.
3. Storage Following Use
   - Dispose of used and left over products including needles and cannulas after procedure.
   - Due to possible risks of contamination, distortion, and infection, left over products are not to be reused.
   - The reuse of this product, a single use medical device, is prohibited.

E Precautions During Use

1. Warning
   - The product is to be used only for intradermal injections.
   - This product is not to be injected into blood vessels. Unintended introduction into blood vessels could cause occlusion, ischemia, tissue necrosis, etc.
   - When injected into blood vessel, this may result in serious side affect such as blindness, it is suggested not to use this filler around middle of forehead having a thin skin and a high probability that injected into blood vessels. So pay special attention when operating.
   - Stop injection if the injection site becomes pale, and massage the treatment site until it returns to a normal color.
   - The product is not to be used on patients with bleeding disorders or those taking thrombolytics or anticoagulants.
   - This product is not to be re-sterilized.
   - This product is not to be mixed with other products before injection.
2. Precautions Regarding Age, Sex, and Physical Conditions
   - Do not inject 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.
   - Following injection, the patient should minimize exposure to excessive sunlight or cold until the initial edema and erythema become less severe.
   - There is a risk of inflammation of the injection site should the injection area be subject to laser treatment, chemical peeling, or any other procedure based on dermal response before the treatment site is fully healed. The use of this product on an area treated with the previous procedures before full healing of the site can cause inflammation.
   - An excessive or too shallow injection can result in the temporary formation of a lump.
   - Safety & Effectiveness for Lip Augmentation are not established.
   - Do not use this product on pregnant or breastfeeding women or children.
3. Precautions Regarding Adverse Effects, Side Effects, Unexpected Responses
   - Erythema, edema, light pain, itching, bruising, tenderness, or other responses generally associated with injections may initially occur following injection. These responses gradually resolve with time.
   - Adverse events studied as part of risk management of related products are as the following
     - 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 vor subclinical herpes infection, acne, granuloma, blistering, clotting, facial edema, rash, dermatitis, scarring, skin 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 hypertrophic scar is not established.
   - The infection site should be treated with adequate treatment or with the removal of the implant. If the symptom is severe, corticosteroid treatment could be effective.
   - The decision for the retreatment of patients who experienced any clinically significant reactions should be made after considering the cause of and seriousness of the reaction.
   - Safety & Effectiveness for long-time using are not established except a period verified through a clinical test.
   - Any side effects should be notified to the surgeon or the manufacturer
4. Other precautions
   - Any injections includes the risk of infection. Keeping an aseptic environment and standard procedures help prevent cross-infection.
   - Procedure on a patient with unattainable expectation is not suitable.
   - Do not use if product is expired or if package is opened or damaged.
   - 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 there is any inflammation, infection, tumor, or any other active form of diseases near the intended injection site.
   - Injection procedure could cause or lead to any latent or subclinical herpes virus infection.
   - Patients who are using substances that affect platelet function, such as aspirin and non- steroidal anti-inflammatory drugs may, as with any injection, experience increased bruising or bleeding at injection site.

F Symbols

REF	Catalogue number	LOT	Batch code
	Do not re-use		Date of manufacture
	Caution		Use-by date
	Fragile, handle with care		Manufacturer
	Temperature limit		Do not use if package is damaged
	Do not resterilize	UDI	Unique device identifier
	Keep away from sunlight		Consult instructions for use
STERILE	Sterilized using steam heat	MD	Medical device
	Single sterile barrier system with protective packing outside		

G Mass / Packing Unit

- Refer to bottom of the package

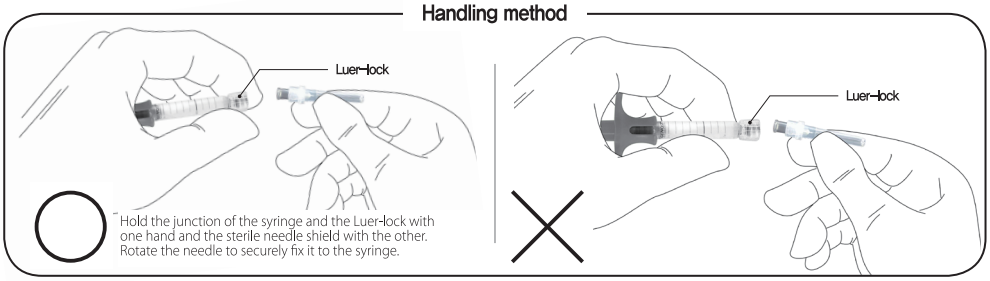
H Storage

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

I Expiration Date

- Refer to bottom of the package

Handling method



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