MONALISA SKIN PLUS

Hyaluronic Acid Dermal Filler

Device Generic Name

Injectable Dermal Filler

Description

MONALISA Skin Plus is transparent gel of stabilized hyaluronic acid of non-animal origin.
MONALISA Skin Plus 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.

Composition

· Hyaluronic acid gel ..... 32 mg/mL for MONALISA Skin 32+
..... 50 mg/mL for MONALISA Skin 50+
· Phosphate Buffered Saline ..... q.s.

Intended Use

MONALISA Skin Plus is intended to temporarily improve facial wrinkles in patients over 21.

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.
· **Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.**

2. Procedures of Use

· Open the package containing the syringe.
· Hold the luer-lock portion of the syringe with one hand and use the other hand to twist the cap counterclockwise to remove the cap.
· Using sterile needles and cannula, approved medical devices matching the Luer-lock specifications of syringes, is essential for safe handling.
· Properly connect the needle to the syringe of this product. If the connection is incomplete, there is a possibility that the syringe and needle may become separated during injection.
· 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.
· The physician slowly injects the injection solution into the area where the procedure is needed using an appropriate injection technique.
· 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.
· If the injection site is swelling, remove the swelling 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

· Store at room temperature between 2 and 25℃ and do not freeze or heat.
· This product is a single-use medical device, after the procedure, dispose of used products as medical waste.
· **Do not reuse.**

Precautions During Use

1. Contraindication

· This product is not injected into blood vessels. Unintended introduction into blood vessels could cause blindness, occlusion, ischemia, tissue necrosis, stroke, etc.
· When injected into the blood vessels, this may result in serious side effects such as blindness suggested not to use
this filler around the middle of the forehead having thin skin and a high probability that injected into blood vessels. So especially pay attention when injecting.
· The product not be used on patients with bleeding disorders or those taking thrombolytic agents or anticoagulants.
· It should not be used in patients with hypersensitivity to components of this product (Sodium hyaluronic acid).

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 or breastfeeding women or children (under the age of 21).

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, lumping, 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 atrophy, reduction of a 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 inflammation 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.
· Any side effects should be notified to the physician or the manufacturer

4. Other Precautions

· 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.

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

· MONALISA Skin Plus is not known to be safe for pregnant women, 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

· 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.

9. Absorbable Information

· MONALISA Skin Plus 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, 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

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

Expiration Date

Refer to the product label.

Symbols

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

MS-P3363/IFU-DA2401 (Rev.0,2406)

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