MONALISA B

Hyaluronic Acid Body Filler

Instruction for Use

Product name: MONALISA B
Before using product, read the following information thoroughly

Description

MONALISA B is sterile, transparent gel of stabilized cross-linked hyaluronic acid of non-animal origin with 0.3% lidocaine. MONALISA B is supplied in a COC syringe. The contents of the syringe have been sterilized using moist heat and pressure. The product is for single use only.

Composition

- Cross-linked hyaluronic acid gel…….…. 24 mg/mL
- Lidocaine HCl……..… 3 mg/mL
- Phosphate Buffered Saline, pH 7.0 ……..…… q.s.
- Each syringe contains 10mL of MONALISA B.

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.
- 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 Procedures

- 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.

Precautions during use

1. Contra-Indications

- 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 effect 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.
- This product contains lidocaine and should not be used for patients with lidocaine allergy.
- This product is not intended to be used in patients with known hypersensitivity to lidocaine or aesthetic of the amide type.

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2. Precautions regarding age, sex, and physical conditions

- Do not injection 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 for undesirable effects

- The medical practitioners must inform the patients that potential side effects associated with use of this product can occur immediately or may be delayed.
- These include:
  Unintended injection into blood vessels could cause blindness, occlusion, ischemia, tissue necrosis, stroke, etc.
  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 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 reation.
- 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 include 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.

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, injection, 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 an injection, experience increased bruising or bleeding at injection site.

6.Absorbable information

- MONALISA B is bio-absorbable which means that they will gradually be absorbed into the body. As the gel breaks down, water takes its place, and when totally absorbed, the MONALISA B gel disappears unnoticed from the body.
- How long a MONALISA B treatment holds its effect is very individual, but will typically last six to twelve months. This depends on many factors, such as your age, skin type, lifestyle, and muscle activity, as well as on the injection technique.
- There could be some delayed side effects for absorbable of injectable dermal fillers such as inflammation, erythema or edema.

Mass/Packing Unit

Refer to bottom of the package

Storage

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

Expiration Date

Refer to bottom of the package

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		

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"부작용 보고 관련 문의처(한국의료기기안전정보원, 080-080-4183)"

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