LUCA

cella

With Lidocaine

[COMPOSITION]

Cross-linked sodium hyaluronate.....24mg/mL
Lidocaine Hydrochloride.....3mg/mL
Phosphate buffered saline.....q.s

[DESCRIPTION]

This product is a biomaterial for tissue restoration. Syringe is filled with 0.3% Lidocaine hydrochloride with a derivative of cross-linked sodium hyaluronate originated from bacterial fermentation gel. It is injected into the skin layer of facial wrinkles. It is used for temporal wrinkle improvement. Lidocaine has the effect of reducing pain during treatment.

- Item Name : Biomaterial for tissue restoration
- Product Name : LUCA CELLA
- Expiry date : See exterior package
- Purpose of use : Hyaluronic acid with lidocaine is injected into the subcutaneous layer to temporarily improve the wrinkles of the adult's face through physical restoration.
- Storage : Room temperature (2°C~25°C), avoid direct sunlight and freezing
- Package unit : 1 pre-filled syringe and 2 sterile needles per box

[WARNINGS AND INCOMPATIBILITIES]

1) Be sure to understand the user's manual before use so you understand how to use the product, know about its potential side effects, and follow warnings.
2) Inspect the outer and inner packaging before use, looking for damage and defects, and do not use if there is any damage or defects found on the product.
3) Check the expiration date on the product label and do not use expired products.
4) Because it is a disposable sterile product, it must not be reused and do not try to re-sterilize it.
5) Do not bend or break the needle for use.
6) Do not use in the following cases:
   - Patients with hypersensitivity to lidocaine or amide type local anesthetics
   - Patients with hypersensitivity to hyaluronic acid
   - Patients with skin diseases, allergies, inflammation, or any other similar disease
   - Patients with a history of severe allergy or hypersensitivity (anaphylaxis)
   - Patients who tend to show or develop hypertrophic scars
   - Patients with a history of/ongoing autoimmune disease
   - Sites with ongoing infectious skin disease or dermatitis (pimples, herpes, etc.)
   - Patients with bleeding-related disorders or diseases
   - Patients with bacterial allergy
   - Pregnant or lactating women
   - Minors
7) If injected into blood vessels, serious side effects, such as blindness, may occur. Thus, it is advised not to use the product at a site where the skin is thin and the possibility of being injected into a blood vessel is high, and special attention should be paid during the procedure
8) Do not use this product near blood vessels with the possibility of developing vaso-occlusion (and resulting tissue necrosis).
9) It should not be used together with other products or medications.
10) It should not be used in combination with laser treatment, chemical peeling, dermabrasion, or other surgical methods.
11) It should not be used on sites (breasts, reproductive organs, etc.) that are not permitted, and excessive use should be avoided.
12) It should be used only on the intended site.
13) It should not be injected to epithelium.

[CAUTIONS]

1) The procedure should be performed by a doctor who has been sufficiently trained for treatment using this product.
2) Before the procedure, the doctor should provide the patient with sufficient explanation on dermatological indications, incompatibilities, and potential side effects.
3) It should be verified whether or not there was any damage in the sterility of the product before use.
4) The patient's skin condition should be considered first, if they have any skin disease, it should be sufficiently treated before use.
5) It should not be used until infection or inflammation is controlled or resolved.
6) The procedure should be performed in an operating room in which unintended mistakes or side effects can be handled immediately.
7) If there are pimples or big pores, the product can be leak. So these issues should be sufficiently recognized before use.
8) Before the procedure, the injection site and surrounding tissue should be massaged, then be sufficiently disinfected.
9) Upon injection, if it is injected to the epithelium, the injection site will become protruded. Thus, it should be injected into dermis.
10) Injection on a patient who has had herpetic eruption may make the herpes reoccur.
11) The safety of patients with sensitivity to keloid formation or hyperpigmentation has not been established.
12) When used in combination with a drug that has a structural relation with other local anesthetics or amide type local anesthetics, attention should be paid as systemic toxic reactions may occur.
13) When used in combination with the local application of dental block or lidocaine, the total amount of lidocaine should be carefully determined. A high-dose of lidocaine (400mg or more) may cause an acute toxic reaction appearing as a symptom affecting the central nervous system and ECG.
14) Lidocaine may cause local redness or hypersensitivity.
15) Before the procedure, it is prohibited for patients to take aspirin or excessive vitamins.
16) Lidocaine should be carefully used for patients with epilepsy, lowered ECG, or severely declined hepatic or renal function.
17) It is recommended for patients to not wear makeup for 24 hours after the procedure, and long-term exposure to sunlight, ultraviolet light, or extreme coldness should be avoided as well as use of a sauna for two weeks after procedure.

[INTERACTIONS]

Hyaluronic acid is a substance that may cause precipitation by quaternary ammonium such as benzalkonium chloride, a sanitizer/disinfectant, and chlorohexidine, so it should not come into contact with these substances or surgical instruments contacted with these substances.

[SIDE EFFECTS]

The practitioner should sufficiently explain to the patient that the following symptoms may be shown immediately after the injection of the product or after a certain period of time and should report to the distributor if such symptoms appear.

1) Potential Side Effects
   - Bruise, inflammation, edema (swelling), pain, softness, itchiness, eruption of a rash, fever, or skin discoloration
   - Uplift (nodules) at the procedure site beneath the skin such as granuloma (bump) that needs to be removed by surgery
   - Inflammation responses such as infection, etc.
   - The procedure site can be opened and the filler leaks through it.
   - Scaring, allergic reaction, sclerosis, and tissue necrosis at the injection site
   - Movement to another location from the filler injection site
   - Permanent bump on the face
   - Impaired blood supply caused by injection into blood vessels or injury on skin or lips
   - Visual impairments, including blindness, when used on the nose or around the nose
2) After injecting hyaluronic acid, pay close attention to abscess, and hypersensitivity which may occur.
3) In case of inflammation or other side effects persisting for more than one week, the patient should consult their doctor at once and get treatment.
4) The following adverse events have been reported in lidocaine injection (for systemic use).

① Shock

- Shock may occur. Thus, the patient should be carefully observed, and if there is a decrease in blood pressure, pale complexion, abnormal pulse, or respiratory depression are observed, the injection should be stopped at once, and appropriate treatment should be administered.

② Malignant hyperthermia

- Severe malignant hyperthermia may rarely occur, accompanied with unexplained tachycardia, arrhythmia, blood pressure fluctuations, sudden rises in body temperature, muscle stiffness, darkening of blood (cyanosis), hyperventilation, sweating, acidosis, hyperkalemia, and myoglobinuria (red urine). If these symptoms accompanied by malignant hyperthermia appear during administration of this drug, the injection should be stopped immediately, and appropriate treatment should be administered, such as intravenous injection of

dantrolene sodium, systemic cooling, excessive ventilation with pure oxygen, and acid-base equilibrium correction. In addition, these symptoms may cause frequent renal failure, so keeping a proper amount of urinary output should be encouraged.

③ Central Nervous System

- Poisoning symptoms such as tremors or convulsions may occur. Thus, the patient should be sufficiently observed, and if such symptoms appear, the administration of the drug should be stopped immediately, and appropriate treatment should be given, such as administration of Diazepam or short acting barbiturates (thiopental sodium).
- Drowsiness, anxiety, excitement, anopia, dizziness, nausea, and vomiting may occur. Thus, the patient should be sufficiently observed and attention should be paid to prevent the progression into symptoms of shock or poison. If necessary, appropriate treatment should be administered.

④ Hypersensitivity

- Skin symptoms such as hives, edema, etc. may occur.

[METHOD OF USE]

1) Preparatory requirement before use

①This product is medical device therefore it shall be used by licensed medical professionals.

②Before using it the doctor shall provide sufficient explanation to the patient about indications, contraindications and potential side-effects of this product.

③Before its use it is necessary to check and see if sterilized condition is damaged or not.

④Check the effective period on the label of the product

2) Sequence of manipulation and method of use

①Before use, disinfect the part subjected to injection thoroughly.

②Connect the needle enclosed in this product and then remove air, if there is any. (See ASSEMBLY OF NEEDLE TO SYRINGE)

③A certain amount of this product is injected into skin where the injection is required according to judgement of medical professional and when required repetitive injection may be made.

④After injection the part where injection is made shall be shaped by tip of hands.

⑤Regular additional injection is required or demanded in order to maintain improved condition

3) Method of storage and management after use

①This product is a disposable sterile medical device and should not be reused or re-sterilized.

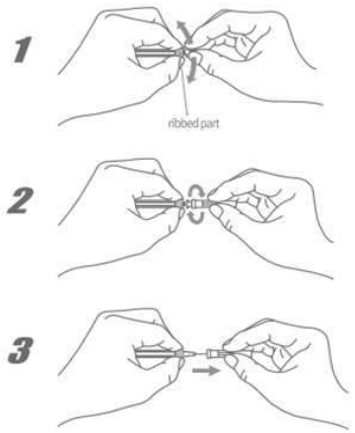
②Used syringes, needles, and gel leftover after treatment should be discarded.

[ASSEMBLY OF NEEDLE TO SYRINGE]

For safe use of the product, it is important that the needle is properly assembled to the syringe. Improper assembly may result in separation of the needle and syringe during injection. (See diagram 1, 2 and 3.)

1) Firmly hold the white colored ribbed part of the luer-lock adaptor of the syringe between the Thumb and the index fingers. Break the protective cap at 90° and remove it with the other hand.
2) Keep holding the luer-lock, firmly push and screw the needle on the syringe clockwise until a resistance is felt. Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level.
3) Next, remove the protective cap from the needle by holding the luer-lock in one hand, the protective cap in the other, and pulling the two hands in opposite directions.

[DIAGRAM]



[SYMBOLS USED ON LABELING]

	Manufacturer
	Use by date
LOT	Batch code
	Do not re-use
	Do not use if package is damaged
	Caution, Consult accompanying documents
2℃ 25℃	Temperature limitation (2°C ~ 25°C)
	Fragile, handle with care
	Keep away from rain
	Keep away from sunlight
STERILE	Sterilized using steam
	Do not resterilize
	Consult instruction for use
	Needle
STERILE EO	Sterilized using ethylene oxide

[MANUFACTURER]

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With Lidocaine