









CEI

LUMIFIL

with Lidocaine



Medical Device

Cross-linked Hyaluronic Acid Dermal Filler with Lidocaine

LUMIFIL

with Lidocaine

INSTRUCTIONS FOR USE

| Product | Cross-linked Hyaluronic Acid | | | | |
|--------------|------------------------------|-----|--------------|--|--|
| Name | Dermal Filler with Lidocaine | | | | |
| | 1pre-filled syringe / 1box | | | | |
| Model Name | L-KISS | 1ml | 2×30G | | |
| & | | 1ml | 2×27G | | |
| Packing Unit | | 1ml | 1×25G, 1×27G | | |

Indicated on the package

1~30°C, Protect from direct sunlight and freezing

COMPOSITION Cross-linked hyaluronic acid 1) -....20mg/mL Lidocaine hydrochloride · Phosphate buffered saline pH 7...

DESCRIPTION

LUMIFIL with Lidocaine is a sterile pyrogen-free LUMIFIL with Lidocaine is a sterile pyrogen-free physiological gel of cross-linked hyaluronic acid, of non-animal origin with lidocaine hydrochloride. It is a colorless, odorless and highly viscous aqueous gel. LUMIFIL with Lidocaine is presented as a sterile gel in a single-us syringe.

INTENDED PURPOSE

LUMIFIL with Lidocaine L-KISS is used to correct moderate wrinkles and restore volume in the face by injection into the middle part of dermis laver, LUMIFIL with Lidocaine L-LITE is mainly used for the correction of very thin superficial lines and is injected into the upper part of the dermis. LUMIFIL with Lidocaine L-MAX is used for the correction of moderate to severe facial wrinkles and folds and for age-related midface contour deficiencies in patient and is injected into the deep layer of the dermis. All models are only indicated for patients over the age of 21.

Ref.) 1) Cross-linked hyaluronic acid: 'Sodium hyaluronate' and '1,4-Butanediol diglycidyl ether are used to synthesize cross-linked hyaluronic acid.

INDICATIONS

LUMIFIL with Lidocaine is indicated for correction of facial wrinkles and folds, and facial tissue augmentation by injecting into the dermal layer of the skin. The addition of lidocaine provides a pain-relieving effect during treatment.

CONTRAINDICATIONS

· Do not inject LUMIFIL with Lidocaine into the eye Do not inject LUMIPIL with Lidocaine into the eye contours (eye circle or eyelids).
 Do not inject LUMIPIL with Lidocaine into the blood vessels (intravascular).
 LUMIPIL with Lidocaine must not be used in:

- women who are pregnant or breastfeeding.
 people under age of 21.
 patients who are known to be hypersensitive to
- patients who are known to be hypersensitive to hyaluronic acid.
 patients who tend to develop hypertrophic scarring.
- LUMIFIL with Lidocaine must not be used with laser therapy, chemical peeling or dermal abrasion.
- · LUMIFIL with Lidocaine must not be used in areas presenting cutaneous inflammatory and infectious
- processes.

 Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine is used concurrently. High doses of lidocaine (more than 400mg) can cause acute toxic reactions manifesting as symptoms affecting the
- central nervous system and cardiac conduction. Lidocaine should be used with caution in patients Eladocarine should be used with caution in patients receiving other local anesthetics or agents structurally e.g., certain anti-arrhythmics, since the systemic toxic effects can be additive.

 Lidocarine should be used cautiously in patients with
- epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction. Peribulbar injections of local anesthetics carry a low risk of persistent ocular muscle dysfunction.

DOSAGE AND ANMINSTRATION

Before the treatment, the patient's suitability for the treatment and his/her medical history should be assessed. Patients should be informed of the indications assessed. Patients should be informed of the indications of LUMIFIL with Lidocaline as well as its contraindications and potential adverse events before they are treated. The area to be treated must be thoroughly disinfected and the product should be injected under sterile conditions. Keep the product at room temperature for 30 minutes prior to injection. Before injecting, press on the plunger of the syringe until a small drop is visible at the tip of the needle. Inject slowly to the dermis using the appropriate technique, either the linear threading technique or a series of punctual injections with the needle provided. The amount of LUMIFIL with Lidocaine injected per wrinkle will depend on its severity. If blanching is observed, i.e. the skin turns into a whitish color, the injection should be stopped immediately and the area should be massaged until it returns to normal color. After the injection, massage lightly on the treated site to conform to the contour of the surrounding tissues. Retouching of the treatment can be done immediately minutes prior to injection. Before injecting, press on the

Retouching of the treatment can be done immediately or a few weeks after the first injection.

WARNING

LUMIFIL with Lidocaine is intended for use as an intradermal implant.

intracermal implant.

Confirm that the product has not expired and the sterility has not been compromised before use, the product is for single use only; do not re-use.

Re-use of the product can depress performance of the

device and may lead to severe cross-infection. Used needles and syringes must be disposed into a collector designed for this purpose.

PRECAUTIONS FOR USE

- · LUMIFIL with Lidocaine is packaged for single patient
- use. Do not re-sterilize.

 Do not use if package is opened or damaged.

 LUMIFIL with Lidocaine should not be injected into an area where there is an implant.

 LUMIFIL with Lidocaine should not be mixed with other products before implantation.
- Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.
- Do not use in patients with bleeding disorders or patients who have undergone therapy with thrombolytic anticoagulants, or inhibitors of platelet aggregation in the preceding 2 weeks. In the same way, it is recommended to avoid taking aspirin, non-steroidal anti-inflammatory drug or high dose vitamin C the week before the injection
- Patients should be recommended not to apply make-Patients should be recommended not to apply make-up for 12 hours after the injection and to avoid prolonged exposure to sunlight, UV, as well as extreme cold and heat for two weeks after the injection. If the needle is blocked, do not increase the pressure on
- the plunger rod but stop the injection and replace the

(2024.02 / Rev.No.02)

- Physicians must inform patients about the potential adverse events, which could be immediate or delayed after the injection. These adverse events include but are not limited to:
 Inflammatory reactions such as redness, swelling and
- tenderness occurring at the injection site. These reactions may last for two weeks. Nodules formation or indurations are also possible at the

ADVERSE EVENTS

- Nocules formation or indurations are also poin injection site.

 Haematomas.

 Staining or discoloration of the injection site.

 Poor effect or weak filling effect.
- Cases of glabellar necrosis, abscess formation, granuloma and immediate or delayed hypersensitivity have been reported in the literature following hyaluronic acid injection. It is therefore important to take such possible complications into account.

Patients must report inflammatory reactions which persist for more than one week or any other secondary effect which develops to their practitioner as soon as possible. The practitioner should treat these as

appropriate.

Any other undesirable side effects associated with injection of LUMIFIL with Lidocaine must be reported to the distributor and/or to the manufacturer.

STERILIZATION INFORMATION

Moist Heat Sterilization

SHELF LIFE

3 years from the date of manufacture

EC REP JaviTech e.k. Sachsenhausener Str. 16, 65824 Schwalbach a. Ts., Germany

[Distributor] LUMIFIL UK LIMITED 298 Winwick Road, Warrington, WA2 8HZ, UK Tel: 01925 967131 http://www.lumifil.co.uk

BNC KOREA, Inc.

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UK REP International Associates Limited Centrum House, 38 Queen Street, Glasgow, Lanarkshire, G1 3DX, UK UKRP@ia-uk.com

CET

| 가재명 | LUMIFIL with Lidocaine(CE) | | | PANTONE RHODAMINE RED C |
|----------------|--|------|-------------|-------------------------|
| | 설명서 (MDD/유럽대리인+영국대리인) | | | K 100 |
| 사이즈(mm) | 사이즈(mm) 225x160mm (접지: 56.25x160mm) | | | |
| 원단 (지질/평량) | 모조 60g | | | |
| 코팅 | | | | |
| | | | | |
| 특이사항 (상세기재) | * 2도 인쇄 * 양면인쇄 foot: Arial | 후가공 | | |
| | font : Arial 버전 : 2024.02/Rev.No.02 | | | |
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| | | 수정날짜 | 24.02.26_수정 | |
| 수정사항 | * 니들 CE번호 수정 * EURP 정보 중 연락처 삭제 * BNC KOREA, Inc. 로 수정 * 개정연월 번호 수정 | | | |