# INSTRUCTIONS FOR USE – Lacrifill®

## Lacrifill® Canalicular Gel

Disposable syringe - Sterile Canalicular gel 20mg/ml

### I. DESCRIPTION & COMPOSITION

**Lacrifill®** is sterile, colorless gel composed of non-animal hyaluronic acid (HA) cross-linked with 1,4- butanediol diglycidylether (BDDE) and reconstituted in a physiological buffer. The product is supplied in 1mL syringe (filling volume: 0.6mL), sterilized using moist heat sterilization process.

The pre-filled syringe is assembled with a plunger rod and a finger rest to allow gel placement. It is then packed in a secondary packaging (blister) to protect it from damage during transportation and storage and corresponds to one unit.

**Lacrifill®** is available in boxes of 1 or 10 units. **Lacrifill®** does not include any accessory.

Qualitative and quantitative components of the injected gel:

| Ingredients | Content per g |
|---|---|
| Crosslinked sodium hyaluronate | 20 mg |
| Sodium chloride | 9 mg |
| Potassium dihydrogen phosphate, KH2PO4 | 0.02 mg |
| Disodium hydrogen phosphate dihydrate, Na2HPO4, 2H2O | 0.22 mg |
| Water for Injection (WFI) | ad 1g |

### II. INTENDED USE

**a/ Intended purpose and indication**

**Lacrifill®** is designed to temporarily block tear drainage by the occlusion of the lacrimal canaliculus of one or both eyelids in a given patient, thus maintaining lubricating tears on the surface of the eye.

**Lacrifill®** is intended for use, for up to 6 months, in adult patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations, which can be relieved by blocking of the canalicular system.

**b/ Intended users**

**Lacrifill®** shall only be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law, typically ophthalmologists or optometrists.

**c/ Target population**

**Lacrifill®** is used in adults experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations.

**d/ Use environment**

**Lacrifill®** is intended to be used in clinics/hospitals or private practices.

### III. CONTRAINDICATIONS

**Lacrifill®** is contraindicated for patients with lacrimal outflow obstruction, inflammation of the ocular surface not associated with dry eye, active ocular or periocular infection (for example, dacryocystitis, canaliculitis, conjunctivitis, keratitis) and those who are allergic to hyaluronic acid.

## IV. MODE OF ACTION

**Lacrifill®** is administered into the lower canaliculus of the patient's eyelid using a commercially available lacrimal cannula attached to the 0.6mL pre-filled **Lacrifill®** syringe. **Lacrifill®** is designed to temporarily block (for up to 6 months) tear drainage by the occlusion of the lacrimal canaliculi in a given patient, thus maintaining lubricating tears on the surface of the eye.

## V. PREREQUISITES BEFORE USE AND OPERATING INSTRUCTIONS

Use of sterile gloves is recommended.

**Cannula Preparation**

1. A sterile, disposable or reusable 25–27-gauge lacrimal cannula with Luer-lock connection may be used with **Lacrifill®** injection device. If a reusable lacrimal cannula, is to be used, the cannula should be cleaned and sterilized prior to use for insertion of the gel consistent with the cannula's instructions for use and institutional procedures. Depending on the use of 25 or 27-gauge lacrimal cannula, the extrusion force will be slightly different, requiring more force to provide the same amount of gel using a 27-gauge lacrimal cannula.

2. Prior to punctal irrigation and insertion of **Lacrifill®**, a topical anesthetic agent should be instilled in the conjunctival sac for patient comfort. Punctal irrigation must demonstrate good lacrimal drainage prior to insertion of **Lacrifill®**.

3. To prepare for insertion of the gel, open the box, inspect the packaging for any signs of damage, remove the tray containing the gel-filled syringe, and peel off tray cover. Do not use if packaging has been compromised or device has been damaged.

4. Remove the cap from the gel-filled syringe and attach a sterile lacrimal cannula to the syringe (Figure 1).

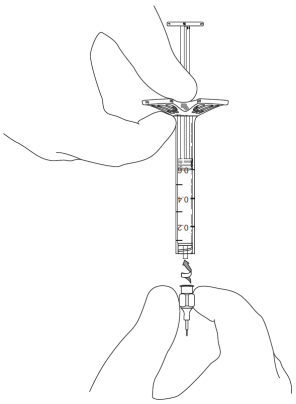


**Figure 1: Attach cannula**

5. Ensure that the attachment is secure (Figure 2). Remove its blister (in case of reusable cannula).

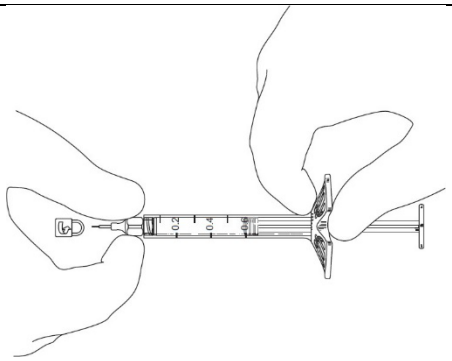


**Figure 2: Twist to lock cannula to syringe**

6. Prime the cannula by pressing the plunger rod forward and extrude 0.1mL of gel into the lacrimal cannula (Figure 3). The volume of gel left in the syringe should be 0.5mL.

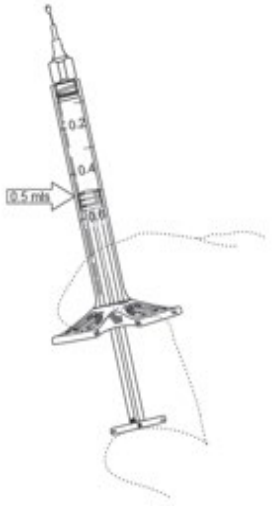



**Figure 3: Prime cannula with 0.1 mL gel**

**Insertion**

7. Place the tip of the lacrimal cannula into the lower punctum of the first eyelid (Figure 4) and insert 0.2mL of gel (Figure 5). The punctum may be dilated if necessary for introduction of the lacrimal cannula. Note: In approximately one-third of cases, gel extrusion from the upper punctum might be observed in which case excess gel can be irrigated from the ocular surface if it obscures the patient's vision.

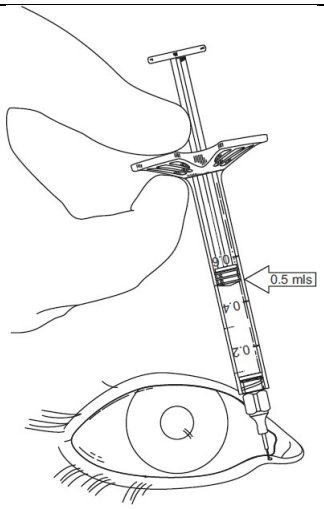



**Figure 4: Place cannula tip in lower punctum**

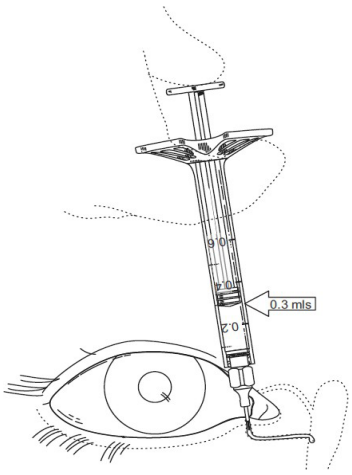



**Figure 5: Deliver 0.2 mL gel into lower canaliculus**

8. For insertion of the gel into the punctum of the second eye, purge the cannula with 0.1mL of gel (the volume of gel left in the syringe should be 0.2 mL) then repeat as illustrated in Figures 4 and 5 above.

9. Remove the lacrimal cannula from the syringe. If using a reusable cannula, clean and re- sterilize using standard procedures consistent with the cannula manufacturer's instructions for use and institutional procedures.

10. Discard the syringe, the disposable cannula if used, any remaining gel, and packaging in accordance with accepted medical practice and applicable local, and national requirements.

**Removal of the Gel**

In case of any adverse event, **Lacrifill®** may be removed. To remove the gel, irrigate the gel from the canaliculus using a syringe filled with sterile saline. Attach a lacrimal cannula onto the syringe, insert the cannula into the canaliculus, and gently irrigate until **Lacrifill®** is removed from the canaliculus as evidenced by free flow of fluid through the lacrimal drainage system and/or the patient's report of swallowing or a fluid sensation in the nose or throat.

## VI. WARNINGS

- As with any procedure, use of **Lacrifill®** carries a risk of infection. Standard precautions associated with injectable materials should be followed. Should an infection occur, flush the gel from the canaliculus.
- If the patient experiences irritation, infection, or epiphora after insertion of **Lacrifill®**, the gel should be removed.
- In the pivotal clinical study, the safety and effectiveness of Lacrifill was characterized over a 6-month period. The safety and effectiveness of the device for longer periods of use has not been established. Therefore **Lacrifill®** should be used for no more than 6 months. After 6 months, **Lacrifill®** should be removed by thorough lacrimal irrigation.
- When removing **Lacrifill®**, ensure that punctal irrigation is sufficiently thorough. If irrigation does not remove the gel, lacrimal probing or surgical exploration may be needed.
- To minimize the risks of potential complications, **Lacrifill®** should only be inserted by health care practitioners who have appropriate training and experience, and who are knowledgeable about the anatomy at and around the punctum and canaliculus.
- Obstruction of the canaliculus should be determined prior to insertion of **Lacrifill®**.
- Do not insert **Lacrifill®** if the canaliculus is obstructed. Care should be used not to perforate the canaliculus during the insertion of the **Lacrifill®**. Perforation may cause pain and increased risk of infection. If perforation occurs, delay the insertion of the gel until the wound heals.

## VII. PRECAUTIONS

**Lacrifill®** is a sterile, colorless gel without visible particulate. If the contents of a syringe show signs of separation and/or appear cloudy or colored, do not use the syringe; notify **Nordic Pharma** immediately at lacrifill-vigilance@nordicpharma.com.

- **Lacrifill®** is provided STERILE for single patient use only, for insertion in one or two lacrimal canaliculus/a during same session to avoid risk of infection.
- Do not re-sterilize the syringe containing the gel.
- Do not insert more or less than 0.2mL of gel into each lower punctum unless the canalicular anatomy of a given patient requires it.
- Use the device prior to the expiration date printed on the label.
- Prior to use, inspect the package and device to verify that there is no damage to the device or package. Do not use the device if the device or packaging appears open or damaged.
- Failure to comply with the cannula attachment instructions could result in cannula disengagement and/or product leakage at the Luer lock and cannula hub connection.
- Prior to punctal irrigation and insertion of **Lacrifill®**, a topical anesthetic agent should be instilled in the conjunctival sac for patient comfort.
- Do not prime more or less than 0.1mL of gel before insertion in each lower canaliculus.
- Inadequate or excessive ejection force, or improper technique used to insert **Lacrifill®** into the lower canaliculus may cause patient discomfort.
- After use, dispose of the syringe in accordance with accepted medical practice and applicable local, and state requirements. If a reusable lacrimal cannula has been used, it should be cleaned and re-sterilized using standard procedures consistent with the cannula manufacturer's instructions for use and institutional procedures.
- As with any punctal or canalicular plug, **Lacrifill®** may enhance the effects of ocular medications used on the eye. Depending on the type of medications being used, dosage may need to be adjusted accordingly.
- The clinical performance of **Lacrifill®** has not been established in the following conditions/patient populations:
  - Pregnancy and breastfeeding.
  - Pediatric patients.
  - Use of ophthalmic cyclosporine (Restasis) within 6 months or lifitegrast (Xiidra) within 3 months.
  - Corneal transplant.
  - Ocular surgery (such as cataract surgery or LASIK) within six months.

- Current systemic infection, uncontrolled autoimmune disease, uncontrolled immunodeficiency disease.
- Significant corneal or conjunctival scarring, pterygium or nodular pinguecula; current ocular infection (except mild blepharitis), conjunctivitis or inflammation not associated with dry eye; anterior (epithelial) basement membrane corneal dystrophy or other clinically significant corneal dystrophy or degeneration; history of ocular herpetic infection; evidence of keratoconus; lid or lacrimal cancer.
- Active severe systemic allergy, seasonal allergies, rhinitis or sinusitis requiring treatment (i.e., antihistamines, decongestants, oral or aerosol steroids).
- Use of steroids, including administration by systemic or topical ocular routes.
- Ectropion.

## VIII. POTENTIAL UNDESIRABLE SIDE EFFECTS

- (Eyelid) pain
- Allergic reactions
- Blepharitis
- Canaliculitis
- Conjunctivitis
- Corneal ulceration
- Dacryocystitis
- Distal migration
- Epiphora
- Foreign Body Sensation
- Itching
- Local infection
- Local irritation
- Loss / Partial extrusion
- Punctal granuloma
- Swelling

## IX. HOW LACRIFILL IS SUPPLIED AND STERILE CONDITIONS

**Lacrifill®** is supplied in a syringe containing 0.6mL of gel for possible insertion of both eyes of a single patient during the same session. The contents of the syringe are sterile by moist heat method. Do not re-sterilize. Do not use if packaging is open or damaged.

## X. EXPIRATION DATE, AND STORAGE, HANDLING AND DISPOSAL

**Lacrifill®** has a shelf life of 24 months. **Lacrifill®** must be used prior to the expiration date on the package. Store at a temperature of +5ºC up to +25ºC. Protect from sunlight. Refrigeration is not required.

After opening, discard any unused material of **Lacrifill®** according to the institutional policies.

## XI. VIGILANCE AND POST-MARKET SURVEILLANCE

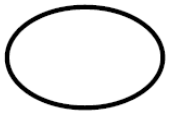
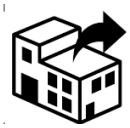
Any serious incident that has occurred in relation to the device must be reported to **Symatese** or **Nordic Pharma** as distributor and the competent authority of the Member State in which the user and/or patient is established.

Notify **Nordic Pharma** and **Symatese** immediately at lacrifill-vigilance@nordicpharma.com.

## XII. EXPLANATION OF SYMBOLS

| DESCRIPTION | SYMBOL |
|---|---|

| | | | |
|---|---|---|---|
| | CE marking in compliance with Medical Device Regulation (EU) 2017/745 |  | |
| | Catalog number |  | |
| | Batch code |  | |
| | Use by date |  | |
| | Manufacturer |  | |
| | Sterilized using steam or dry heat |  | |
| | Temperature limits for storage |  | |
| | Consult instructions for use |  | |
| | Do not use if package is damaged and consult instructions for use. |  | |
| | Single-patient, multiple use (during the same session) |  | |
| | Do not resterilize |  | |
| | Medical Device |  | |

| | |
|---|---|
| Keep away from sunlight |  |
| Single sterile barrier system |  |
| Single sterile barrier system with protective packaging outside |  |
| Fragile, handle with care |  |
| Unique Device Identifier |  |
| Distributor |  |
| Manufacture date |  |
| Keep dry |  |

**Distributed by:**

***Nordic Pharma***

Nordic Group B.V.

Siriusdreef 41, 2132 WT Hoofddorp, Netherlands

**Manufactured by:**

***Symatese***

SYMATESE SAS

Z.I. Les Troques 69630 CHAPONOST FRANCE.

This IFU is also available in electronic form, on the legal manufacturer website

https://www.symatese-lab.com/lacrifill-info

Latest approval date: 2025-03-31, REV. 04 - LACB14A