Sofiderm®

DERM PREFILLED SYRINGE

CROSS-LINKED SODIUM HYALURONATE GEL FOR PLASTIC SURGERY

Instruction For Use

CE 2460

Composition

Sofiderm® Derm prefilled syringe is at the concentration of 20±3mg/ml, including phosphate buffer (pH 6.8-7.6; contains sodium chloride). It is supplied in a sterile single use syringe with a luer-lock fitting, and sterilized by heat steam sterilization.

The number of units per package and the volume of each syringe are stated on the outer package. The patient record label is a part of the syringe label, in order to ensure the traceability of the product.

Description

Sofiderm® Derm prefilled syringe is a sterile biodegradable, viscoelastic, isotonic, homogenized and transparent injectable gel implant. It is a kind of stable sodium hyaluronic acid of non-animal origin, intended for single use only.

This kind of cross-linked hyaluronic acid provides a prolonged half-life compared with naturally formed hyaluronic acid, which undertakes the physiological breakdown in subcutaneous tissues.

Native cross-linked HA contains larger and more stable molecules with similar biocompatibility and viscoelastic filling properties so that it has longer residue time in the tissues. Large molecular network structure of HA combines with large amount of water to form hydrogen bonds and constitute matrix in the body, which have the functions of regulating the osmotic pressure and macromolecules, forming a physical barrier and regulating the action of cell.

HA molecules have different physiological roles in different tissues, such as water conservation in skin; lubrication action in synovial fluid; main regulator of permeability in vessel wall. In addition, as a kind of polyanion electrolyte, HA molecules have a large amount of negative charge, which can adjust the concentration of positive and negative ions around and control the activity of enzymes.

The package for **Sofiderm® Derm prefilled syringe** contains one syringe with **Sofiderm® Derm** gel.

The following type of needle can be used with the **Sofiderm® Derm prefilled syringe**: sterile, 27G × ½".

Specification: 0.5ml; 1ml; 2ml.

Intended use

Sofiderm® Derm prefilled syringe is an injectable implant used for the treatment of cleft lip and eyelid malposition.

Mode of action

The lifting capacity that originates from hyaluronic acid, increases the stability due to its propensity to attract high volume of water. This property persists even during its eventual degradation.

Warning

- Verify the integrity of the syringe and the expiry date before use.
- Do not inject into glabellar regions. Use of the products in these areas has been complicated by unintentional intravascular injection resulting in embolization and symptoms consistent with ocular vessel occlusion, such as blindness.
- The product is packed for single-patient use. The syringe and any content can not be used on another patient. Do not reuse. The cross infection and cellulitis can occur if the product is reused.
- Do not resterilize. Do not use if package is opened or damaged. Those situations carry a risk of infection.
- The product must not be injected into blood vessels. Introduction of product into the vasculature may lead to embolization, occlusion of vessels, ischemia or infarction.
- Do not use any other needle or syringe except from the manufacturer.
- Do not inject with other products.
- If the blanching is observed during injection (i.e. the overlying skin turns white), stop injecting at once, then massage and warm the area, seek the advice from experts.
- Dispose of all packaging and contents appropriately in accordance with local guidelines after use.
- Products must be injected into non-inflamed, disinfected, healthy skin. The injection technique is only used by doctors who have been trained with specific injection technique.

Precaution

- Normal infection control precautions should be the same as other injections.
- The product must not be injected into areas where permanent implants are inserted.
- Special attention should be paid to the use of limited soft tissue when treating facial areas.
- If a chemical "peeling" or other procedure based on a dermal active response can be created after injection, there is a theoretical risk of reaction at the implant site. The same can happen if the product is used before the skin completely recovers from this type of procedure.
- Before treatment, thorough consultation should be conducted between practitioners and patients. The consultation should cover indications, expected outcomes, potential side effects and complications, anaesthesia and postoperative care advice.
- Defects should not be overcorrected. In cases where a large amount of the product is required, the treatment is recommended in two separate applications.
- Patients with anti-coagulants or those who receive platelet aggregation inhibitors (e.g. ASS), thrombolytics or anticoagulants should consult their doctors as they have a higher risk of haematoma (severe bruise) after injection.
- Practitioners should be suitably trained to offer this treatment and manage its potential side-effects and complications.
- Based on preclinical studies, patients should be limited to 20 ml of product per 70 kg body mass per year.

Contraindications

- Patients with a history of hypertrophy or current streptococcal infections, active skin disease, inflammation or other infections.
- Patients with a history of autoimmune diseases or who have received immunotherapy.
- Patients are hypersensitive to hyaluronic acid.
- The product has not been tested on pregnant women, breastfeeding women, or children. There is no evidence that the product is safe for these groups.
- Available clinical data confirm the safety and efficacy of the product in adults. There is no clinical data available for people under 18. Therefore, the product is not recommended to such a group.
- Patients with anti-coagulants or those who receive platelet aggregation inhibitors (e.g. ASS), should consult their doctors.
- The product should be kept away from children.
- Patients with bleeding disorders.
- Patients who take thrombolytics or anticoagulants, or those who take inhibitors of platelet aggregation in the preceding 2 weeks.
- Patients with hyperplastic scar and streptococcal infection.
- Do not use with laser treatment, chemical peeling, intensive pulse light or skin abrasion treatment.
- Do not inject in or near anatomic sites with active skin diseases, inflammation, infection or related conditions.
- Do not implant the injection site of other products.

Anticipated adverse events

According to clinical evaluation data, some common reactions such as erythema, swelling, pain, itching, discoloration or sensibility may occur at the site after injection. The typical treatment is spontaneous, occurring one to two days after injection, and it disappears within a week.

The product balances to the normal pressure in the tissues. However, as tissue pressure can sometimes increase (in the case of edemas), or decrease (in the case of dehydration), small but significant changes, such as swelling or wrinkling, may occur in these cases.

In more serious cases, a short course of oral steroids can be helpful. Patients with this reaction must no longer be treated with the product.

The potential risk of accidental injection of substances into the dermal vessels may lead to generating vascular occlusion in the terminal arteries with consequences. There are no reports of this occurrence with the product.

Any adverse event must be notified to the representative of Hangzhou Techderm Biological Products Co., Ltd.

Complications

The estimated incidence of these complications is 0.05% (1 in 2,000 patients), a rare event. No serious adverse events were reported.

- Physical symptoms and conditions at the injection site: inflammation, thanatosis, edema.
- Injure, toxication and complication: bruise.
- Skin and subcutaneous tissue disease: rash.
- Nervous system disease: burning sensation.
- Respiratory, chest and mediastinal disease: sore throat, difficult breathing.

Interactions with other agents

There are incompatibilities between sodium hyaluronate and quaternary ammonium compounds such as benzalkonium chloride solutions. The product should therefore not be in contact with these substances. The product combined with other medicines and devices has not been tested.

Pre-marketing clinical follow-up

Each product contains a Consumer Tracking Form. When a consumer receives an injection of the product, the doctor must record the information and track the safety and effectiveness of the product. If needed, the doctor must take photos and record in the Consumer Tracking Form.

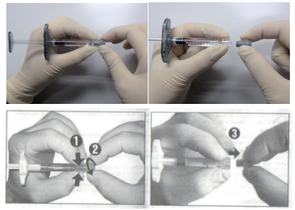
Notes for patients

- If the inflammatory reaction lasts more than a week, or if other adverse events occur, please consult the specialist for treatment immediately.
- No make-up within 12 hours after injection; avoid prolonged exposure to sunlight or ultraviolet rays; no mask, sauna or khan steam.

Instructions for the correct removal of the tip cap:

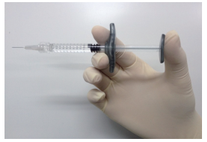
- Hold the luer-lock adapter as shown in ①.
- Unscrew the tip cap carefully with the other hand in an anti-clockwise direction as shown in ②.
- Remove the tip cap as shown in ③. Do not use syringes with open or displaced tip cap in protective packages. In order to use the product safely and simply, it is important to fit in the needle correctly.

Figures for the correct removal of the tip cap:

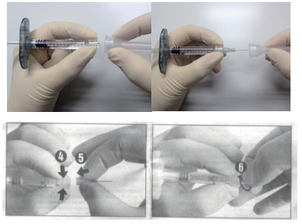


Instructions for the correct insertion of the needle:

- Hold the syringe as shown in ④.
- Hold the needle in position by rotating slightly in a clockwise direction ⑤. Press and rotate 90°(1/4 turn). Do not use any other needles.
- Pull out the protective cap as shown in ⑥.
- During the application, the product should be held as shown in the following figure.



Figures for the correct insertion of the needle:



Storage

- Store at 2°C-30°C. Do not freeze. Protect from the light source.
- Do not use after the expiry date.
- The quality guarantee period is three years.

Document number: KT/CO-AQP-029-F02

Revision: A/6

Date: 2020-09-10

EC REP Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany
Tel: +49 211 30036618
Fax: +49 211 30036619
E-mail: info@caretechion.de

Hangzhou Techderm Biological Products Co., Ltd.
Add: Floor 2, East Building 6, No. 88 Jiangling Road,
Binjiang District, Hangzhou, P. R. China.
Post code: 310051
Tel: 0086 571 87165526
Fax: 0086 571 87165526
Website: www.techderm.com
E-mail: info@techderm.com

International general symbols

Sterilized using steam

Consult instructions for use

Do not re-use

LOT Batch code

Use-by date

2°C 30°C Temperature limit

Keep away from sunlight

Keep dry

Do not resterilize

Do not use if package is damaged

Caution