BEUFILLER

Instruction For Use English

Content

Sterile single-use syringe with sodium hyaluronate solution and single use cannula. Secure attachment of the cannula to the syringe is assured by the Luer-Lock fitting on the tip of the syringe.

Composition

Sodium hyaluronate	24	mg/ml
Sodium chloride (Nacl)	9.0	mg/ml
Disodium hydrogenphosphate (Na2HPO4 x 12H2O)	0.555	mg/ml
Sodium dihydrogenphosphate (NaH2PO4 x 2H2O)	0.045	mg/ml
Water for injection	ad	1ml

Description

The product is a purified viscous and transparent gel; it is a single use product.
This product is a unique stabilized sodium hyaluronic acid of non animal origin.
The sodium hyaluronic acid is a natural polysaccharide present in the skin, in the subcutaneous and in the connective tissues acting as important structuring element, and equally in the synovial tissue and synovial fluid. The sodium hyaluronic acid is one of the few substances having an identical form in all living organisms.
This product includes 5 models. They are Derm Deep, Derm, Fine Lines, Derm Plus and Sub Skin.
Derm Deep is supplied with a 27G x 1/2'' needles; Derm and Fine Lines are supplied with the 30G x 1/2'' needles; Derm Plus and Sub Skin are not supplied with the needles.

Mode of action

The product allows the increment of the skin and lips volume. It restores the contour of the former and accentuates the shape of the latter so that the desired level of correction can be attained. The implant is naturally integrated in the tissues and as time goes by it will undergo an isovolemic degradation. Medical sodium hyaluronate gel soft tissue filler degradation cycle for 6 months~12 months, observed in clinical trials during the period(≤24 months) with good clinical effect, can effectively improve the skin wrinkles and local depressions.

Sterilization

The product is sterilized by moist heat.
The syringe is sterilized by using ethylene oxide.
The needle is sterilized by using irradiation.

Indication and usage

The product is indicated for facial tissue augmentation. Derm Deep is recommended that the product be used for the correction of deep facial wrinkles and folds, shaping facial contours,

cheeks fullness, chin and lips augmentation. Derm Deep should be injected into the deep layer of dermis and of surface layer of subcutis. Derm is recommended that the product be used for the correction of moderate wrinkles, such as glabellar, oral commissures, lips fullness, pouting and vermilion border. Derm should be injected into the middle part of the dermis. Fine Lines is recommended that the products be used for the correction of thin superficial lines, such as worry lines, periorbital lines, perioral lines. Fine Lines should be injected into the upper part of the dermis.

Better results regarding the deformities of the cutaneous contour will be obtained if its defects can be manually stretched until their complete elimination. The duration of the correction will last depending on the type of defect treated, stress at the graft implant spot, depth of implant within the tissue and the adopted injection technique. More serious defects maybe hard to correct.

Warning

a) The product is to be used only by intradermal or subcutaneous. Do not resterilize this product. Do not mix with the other product.

b) This product is sterile injectable products; the reuse will increase the hazard of bacterial contamination and cross infection risks.

Precaution

Normal precaution measures associated with intradermic injections must be observed. As with any other procedure of the kind, implants are associated with a risk of infection.

The product must not be used close or in anatomic locations where there are active pathologies of the skin, inflammations or related conditions. Do not use this product in association to any other injectable implant.

The product must not be injected in areas where a permanent implant inserted or in patients having unreal expectations.

Patients must be informed that they must not expose the treated region to intense heat (as sun bathing) or extreme cold, at least until the initial light edema and erythema disappear.

If a chemical “peeling” or other procedure based on a dermal active response is to be effected after the implant with this product, there is a theoretical risk of reation at the implant spot. The same can occur if this product is applied before the skin completely recovers from this type of procedure.

There is potential risk of accidental injection of materials in blood vessels of the dermis which might generate vascular occlusion in a terminal artery, with the correspondent consequences. There are no reported cases of this occurrence with this product.

Foreseeable collateral effects

Following this product injection some common reactions to injections may occur. These include erythema, swelling, pain, itching, discoloration or sensibility at the spot. The typical healing is spontaneous, occurring one or two days after the injection is effected is effected into the skin, and within a week if effected into the lips.

The composition of this product is to equilibrate the normal pressure of the tissues. However, as the pressure of the tissues is sometimes altered upwards, as in the case of edemas, or downwards, as in dehydration, a small but significant modification may occur(swelling or wrinkling).

Adverse reactions

There were swelling and hardening at the implant spot, sometimes with edemas at the adjacent tissues. Sometimes, erythemas, sensitivity and more rarely, acne papulae, may occur. These reactions may start right after the injection or after 2~4 weeks. It has been described as begign to moderate, and spontaneously healing within 2 weeks. In the more serious cases, a short oral administration of steroids can be helpful. Patients having presented this kind of reactions must not be treated again with this product.

There is the potential risk that the product maybe injected inadvertently into the dermis blood vessels, which might cause an occlusion of the final arteries, with the surge of characteristic consequences. No cases have been reported with this product.

Any adverse occurrence must be informed to the manufacturer.

Interactions

The product combined with other medicine and devices, has not yet been tested.

Shelf life and Storage

Do not use after the Expiration date.

Store at a temperature of 2-30 ℃. Do not freeze. Protect from light source.

The fitting of the needle

For a safe and uncomplicated use of this product it is important to fit in the needle correctly.

a) Carefully unscrew the syringe needle cap.

b) Carefully hold the needle sheath by its narrowest part and fit in the needle screwing it into the luer-lock until you start feeling some counter- pressure.

c) Hold securely the needle sheath by its widest part. Press and rotate 90° （a quarter of a turn）.

d) Remove the needle sheath.

Usage and dosage

Which Sub Skin、Derm Deep and Derm Plus gel containing larger molecules can be injected into the deep dermis or subcutaneous tissue shallow; Derm gel containing medium-sized molecules can be injected into the middle dermis or deep dermis; Fine lines gel containing the minimum elements can be injected into shallow dermal.

The product's treatment is summarized as follows. Fine lines: wrinkles around eyes and in the superficial layer of eyes, and defect of scared tissues; Derm: lipside wrinkles, brow wrinkles, lip wrinkles, and filling of earlobe, etc. Derm Deep: filling and shaping of the body,plumping of the lips, forehead, chin, etc. Sub Skin: Reshaping of facial profile, filling of large area depression, nose plumping, ect. Derm Plus: Wrinkles of the neck, hands, chest, etc.

Before starting the treatment, a stuffy of the patient's compatibility and her threshold to pain must be carried out. Normally, no anesthesia is needed for wrinkles treatment. For lips augmentation, a nerve blockading anesthesia can be applied. The patient must be informed about the indications, expected outcomes, counter-indications, warnings, precautions and potentially adverse reactions. The spot to be treated must be cleaned with an adequate antiseptic solution.

A very superficial injection may cause discoloration; or, in other word, if the subjacent skin

becomes whitish, the injection must be immediately stopped and the area must be massaged until the skin resumes its normal color, prior to injecting, the embolus must be pushed until a drop shows up at the needle end.

The injection technique regarding its depth and the quantity to be administered may vary. The linear threading technique can be used to carefully raise a wrinkle or a fold, although some doctors prefer a series of punctual injections or a combination of both. During the injection, it is recommended that the top of the needle be directed upward. The needle contour must be visible without its color. Injection this product graft while pulling the needle slowly backward. The injection must be stopped immediately before the needle is withdrawn from the skin to avoid spilling of the product on the injected spot.

If it is to be applied to the lips, an enhanced contour or a volume increase can be achieved.

The defects can be completely corrected at each application, but they must not be overcorrected.If the skin is quite loose, it is recommended that this product be administered in two separate applications.

The area to be corrected must be then massaged to fit the adjacent tissues contour. For each treated area, it is recommended a maximum dose of 2ml pre application. If the treated area swells right after theinfection, apply melted ice on it for a short time. After the first treatment, additional grafts of this product may be necessary to achieve the desired correction. Periodical injections for finishing touches may be necessary to achieve the desired correction.

Remark

a) The right injection technique is crucial for the final result of the treatment. The product graft must only be administered by authorized personnel, according to the local regulations.

b) This product has not been tested neither on pregnant or nursing women, nor on children.

THE SYRINGE, NEEDLE AND ALL OTHER MATERIAL USED MUST BE DISCARDED RIGHT AFTER TREATMNET.

Symbols :

	Do not use if the package is damaged.
	Refer to instructions for use
	Storage temperature
	For single use
	Lot number
	Use until date
	Sterile. The contents of the syringe have been Sterilized by using moist heat.
	Sterile. The needle has been sterilized by using irradiation.
	Manufacturer
	Authorized representative in the European Community.