PROFHILO®

3.2% - 16 mg (H-HA) + 16 mg (L-HA)/1 ml Hyaluronic acid sodium salt

3.2% - 32 mg (H-HA) + 32 mg (L-HA)/2 ml Hyaluronic acid sodium salt

Medical device for intradermal use

Sterile – Disposable

DESCRIPTION

Hyaluronic Acid (HA) ¡s a polysaccharide naturally present ¡n the human body whose primary function is maintaining the correct tissue hydration, thanks to its intrinsic capacity to bind large amounts of water.

Hyaluronic acid sodium salt is composed of repeated disaccharide units of N-acetylglucosamine and sodium glucuronate chains, and is a fundamental component of the extracellular matrix in a majority of tissues including the skin.

PROFHILO® constitutes a buffered physiological solution of high molecular weight (H-HA) and low molecular weight (L-HA) HA. The HA, at both high and low molecular weights used in the device, is obtained through a biofermentation process without chemical modification and therefore, resulting in excellent tolerability.

Furthermore, due to a specific and patented treatment of the solution (NAHYCO Hybrid Technology), the H-HA and L-HA chains, contained in **PROFHILO®**, interact with each other providing unique rheological characteristics and thus allowing the administration of higher concentrations of HA without increasing the viscosity.

The formulation of HA with different molecular weights contained in **PROFHILO®** ¡s based on **Hydrolift®** Action. This innovative approach ¡s aimed at counteracting the physiological reduction of HA in the skin, restoring hydration, elasticity and skin tone, by associating, in a synergic way, deep hydration with the mechanical action of lifting the skin.

The other components of the product are: sodium chloride, sodium phosphate and water for Injectable preparations.

INDICATIONS

PROFHILO® acting through a corrective/filling action of natural and induced cutaneous depressions, intervenes:

- in the physiological process of skin aging, the effects of which include reduced skin hydration, the alteration of elastic fibers and collagen of the dermis, with loss of turgor and skin tone;
- in the dermal tissue repair process, in cases of scars resulting from superficial Cutaneous trauma (e.g. acne and chicken pox scars).

The viscoelastic and hydrating properties of HA, combined with the ability to maintain adequate levels of HA ¡n the cutaneous tissues, rehydrate the skin and create optimal conditions for

preventing and counteracting the skin aging process white favoring tissue remodeling with a subsequent corrective effect on photo and chrono aging damage and any possible scarring of the skin.

HA also plays a role inside the extracellular matrix, creating the physiological conditions for the proliferation, migration and organization of the dermal cellular component. Moreover, the intradermal administration of **PROFHILO®** and its action at the dermal layer rather than the epidermal layer, allows an optimal quantity of HA to be brought directly to the tissue being treated, in order to counteract the cytotoxic action of free radicals on the fibroblasts and on the adipose compartments below, ensuring the efficacy of preventive and corrective esthetic medicine treatments.

The HA used in **PROFHILO®** is produced through the biosynthesis of a natural substrate without further chemical modification. Therefore, PROFHILO® has excellent biocompatibility and its use In the dermis allows integration with endogenous HA which has been reduced and modified due to the physiological aging process of the skin or following superficial cutaneous trauma.

In addition, *in vitro* studies have been performed to identify incompatibilities and / or interactions between **PROFHILO®** and Platelet Rich Plasma (PRP). The results obtained demonstrate that the PRP does not change the rheological behavior of sodium hyaluronate.

PROFHILO® is indicated for treatment of the face and body. However, it is particularly Indicated for treatment of the malar-zygomatic and submalar areas.

An initial cycle of two treatment sessions at 30 day intervals is recommended, followed if necessary by maintenance treatments every 2 months. However, it is suggested to evaluate the specific **PROFHILO®** protocol according to the patients degree of aging.

HOW SUPPLIED

Package including 1 pre-filled syringe with 2 needles 29G x ½" (0.33 x 12 mm), in the following available volumes:

- 1 ml pre-filled syringe - 16 mg (H-HA) + 16 mg (L-HA) of hyaluronic acid sodium salt in 1 ml of buffered sodium chloride physiological solution;
- 2 ml pre-filled syringe -32 mg (H-HA) +32 mg (L-HA) of hyaluronic acid sodium salt ¡n 2 ml of buffered sodium chloride physiological solution;

The pre-filled syringes are sterilized by moist heat.

Needles sterilized with ethylene oxide.

Needle: CE 0197; Manufacturer: Terumo Europe N. V. - lnterleuvenlaan 40-3001 Leuven, Belgium

PRODUCT DESCRIPTION

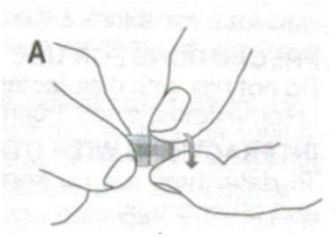
PROFHILO® is supplied in a glass syringe of:

- 1.25 ml containing 1 ml of solution;
- 2.25 ml containing 2 ml of solution.

The contents of the syringe are sterile and pyrogen-free.

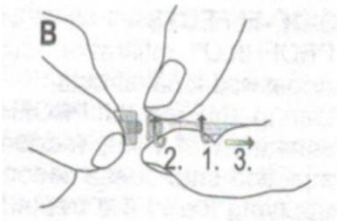
INSTRUCTIONS FOR USE

- Carefully unscrew the cap of the tip of the syringe, keeping the fingers firmly joined to the luer-lock and being particularly careful to avoid contact with the opening (Figure A).



- Keeping a firm grip on the luer-lock mount of the syringe, secure the 29G needle (included in the pack) by turning it until a slight counter-pressure is felt in order to ensure an air-tight seal and prevent leakage of the liquid during administration

(Figure B).



- Inject **PROFHILO®** at room temperature under strict asepsis conditions.

RECOMMENDED INJECTION TECHNIQUES

For a global treatment of the malar and sub-malar areas, ¡t ¡s recommended to identify 5 points (Bio Aesthetic Points) for intradermal administration of **PROFHILO®**. The directions below, in relation to the injection diagram Figure 1, are intended as suggestions to be adapted to the specific needs and the specific morphology of each patient's face.

1) Zygomatic protrusion: make sure to stay at least 2 cm away from the lateral canthus (external corner) of the eye.
2) Nasal base:
   - draw a line connecting the nostril and tragus
   - draw a perpendicular line starting from the pupil
   - locate the injection point at the intersection of the 2 lines
3) Tragus: make sure to stay at least 1 cm anterior to the inferior margin of tragus.
4) Chin:
   - draw a vertical line ¡n the center of the chin
   - draw a perpendicular line one third from the top of the vertical line
   - from the point of intersection move 1.5 cm towards the oral commissure to locate the injection point
5) Mandibular angle: 1 cm above the mandibular angle.

Inject 0.2 ml of product with the bolus technique in the deep dermal/subcutaneous levels.

Massage gently at the injection point.

This injection technique focuses the action of **PROFHILO®** where the skin appears loose and with a loss of turgor and skin tone, concentrating a defined volume of the compound in a few anatomically receptive points, which diffuse progressively through the interstitial spaces bringing to the entire malar, sub-malar area natural and long lasting dermal renewal.

WARNINGS

- The contents of the pre-filled syringe are sterile. The syringe is packaged in a sealed blister pack.
- The external surface of the syringe is not sterile.
- Do not use **PROFHILO®** after the expiry date shown on the pack.
- Do not use **PROFHILO®** if the packaging is open or damaged.
- The point of injection must be on healthy skin.
- Do not inject intravenously, into muscles, tendons or for mammary augmentation.
- Do not mix with other products.
- Do not inject into inflamed areas.
- Do not resterilize. The device is intended for single use only.
- Do not reuse to avoid any risk of contamination.
- Store at 0 ° - 25 ° C away from heat sources. Do not freeze.
- Once opened **PROFHILO®** must be used immediately and discarded after use.
- Keep out of reach of children.
- The presence of an air bubble does not alter in any way the quality of the product.
- After the injection and for the following 3-5 days, advise the patient to avoid UV exposure and to protect the treated area with total sun-block creams.

PRECAUTIONS FOR USE

Do not mix with disinfectants like quaternary ammonium salts or chlorhexidine, since it can form a precipitate.

INTERACTIONS WITH OTHER DRUGS

To date there are no known interactions between **PROFHILO®** and other drugs.

SIDEE-FFECTS

PROFHILO® infiltration outside the dermal layer may cause undesired local effects.

During the use of **PROFHILO®**, symptoms such as pain, the sensation of heat, reddening or swelling may appear at the injection site. These secondary emergences can be relieved by applying ice to the treated area. They generally disappear in a short period of time. Doctors must ensure that patients notify them of any undesired effects which occur after the treatment.

CONTRAINDICATIONS

PROFHILO® must not be used in concurrence with treatments such as laser resurfacing and medium deep skin-peeling.

LAST PATIENT INFORMATION LEAFLET REVIEW

September 2017

TO BE SOLD BY MEDICAL PRESCRIPTION ONLY.

THE INTRADERMICAL INJECTION MAY ONLY BE ADMINISTERED BY A MEDICAL PRACTITIONER.

Year of CE certification 2015