

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) is a polysaccharide naturally present in 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 of microbial origin and it is prepared through a biofermentation process without chemical modification and therefore, resulting in excellent tolerability. The other components of the product include: sodium chloride, sodium phosphate and water for injection.

INDICATIONS

PROFHILO® is intended for treatment of the malar-zygomatic, sub-malar areas face for contours redefinition and laxity remodeling. .

MODE OF ACTION

PROFHILO® exhibits its effect through a corrective/filling action of natural and induced cutaneous depressions, intervening:

- 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 in the cutaneous tissues, rehydrate the skin and create optimal conditions for preventing and counteracting the skin aging process while favoring tissue remodelling 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 structure. 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 administered directly to the tissue being treated to counteract the cytotoxic action of free radicals on the fibroblasts and on the adipose compartments below, aiding in the effectiveness of preventive and corrective aesthetic medicine treatments.

HOW SUPPLIED

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

- 1ml 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 in 2 ml of buffered sodium chloride physiological solution);

The contents of the syringe are sterile and non-pyrogenic.

The pre-filled syringes are sterilized by moist heat.

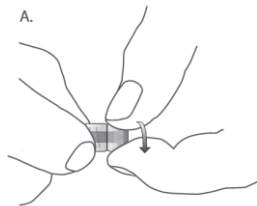
Needles sterilized with ethylene oxide.

Needle: CE 0197;

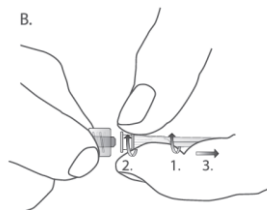
Manufacturer: Terumo Europe N. V. – Interleuvenlaan 40 – 3001 Leuven, Belgium

INSTRUCTIONS FOR USE

- Carefully unscrew the cap of the tip of the syringe, ensuring the luer-lock is firmly held 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 needle (using a 27 – 33G sterile needle provided) by turning it until a slight counter-pressure is felt in order to ensure an air-tight seal. This will prevent leakage of the liquid during administration (Figure B).



- Inject **PROFHILO**® at room temperature using strict aseptic methods.

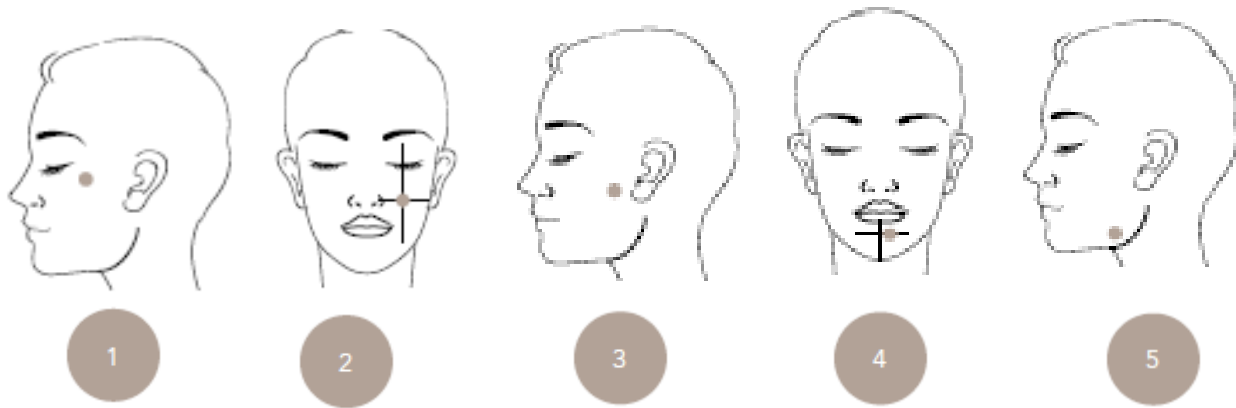
TREATMENT

For a global treatment of the malar and sub-malar areas, it is recommended to identify 5 points (Bio Aesthetic Points) for 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 in 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: 1cm above the mandibular angle

Figure 1



Inject 0.2 ml of product using a bolus technique into the dermal/subcutaneous layer.
Massage gently around the injection site.

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.

Through the suggested treatment, where 5 injection sites are identified for each side of the face, the maximum volume of **PROFHILO®** administered per treatment session is 2ml.

An initial cycle of two treatment sessions at 30-day intervals is recommended, followed if necessary by maintenance treatments every 2 months, for this reason, a total of seven (7) treatments can be administered within a 12 month period. However, it is suggested to evaluate the specific **PROFHILO®** protocol according to the patients degree of aging.

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.

IFU - HiLow hyaluronic acid sodium salt for intradermal use – 11.01.22

- 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 in the syringe barrel 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 SPF 50 sunscreen.

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.

SIDE-EFFECTS AND POSSIBLE ADVERSE EVENTS

During the use of PROFHILO®, symptoms such as pain, the sensation of heat, reddening or swelling, sometimes associated with itching, may appear at the injection site. These symptoms can be relieved by applying ice to the treated area. They generally disappear in a short period of time but may persist for up to 10 days.

Hardening or nodules may appear at the point of injection.

In extremely rare cases, as described in the literature discolouration at the injection site, necrosis of the glabellar area (between the eyebrows above the nose), abscess, granuloma and hypersensitivity may occur after hyaluronic acid injections.

CONTRAINDICATIONS

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

Shelf life: 36 months.

The expiry date indicates the maximum validity of the medical device.

TO BE SOLD BY MEDICAL PRESCRIPTION ONLY.

THE INTRADERMAL INJECTION OF PROFHILO MAY ONLY BE ADMINISTERED BY A HEALTHCARE PROFESSIONAL.

Year of CE certification: 2015

MANUFACTURER:

IBSA Farmaceutici Italia srl

Via Martiri di Cefalonia, 2 - 26900 LODI - ITALY

info@ibsaderma.com



Consult the instructions for use



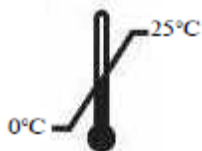
Use by date



Batch code



Do not re-use



Temperature limit



Sterilized using steam



Do not resterilize



Do not use if package
is damaged



Medical device contains a
sterile fluid path that has been
sterilized using steam



Sterilized using ethylene
oxide

Exp.
Expiry