PROFHILO® STRUCTURA

4.5% - 22.5 mg (H-HA) + 22.5 mg (L-HA)/1 ml Hyaluronic acid sodium salt
4.5% - 45 mg (H-HA) + 45 mg (L-HA)/2 ml Hyaluronic acid sodium salt

Medical device for intradermal use

Sterile - Single-use

hydroACTION
liftACTION
CROSS-LINKING

DESCRIPTION

Hyaluronic acid (HA) is a polysaccharide naturally present in the human organism, whose main function is to maintain correct tissue hydration thanks to its intrinsic ability to bind a large amount of water.

Hyaluronic acid sodium salt is formed by repetitive chains of disaccharide units of N-acetylglucosamine and sodium glucuronate and is an essential component of the extracellular matrix in the majority of tissues, including the skin. **PROFHILO® STRUCTURA** is composed of a buffered saline solution of high molecular weight (H-HA) and low molecular weight (L-HA) hyaluronic acid.

The high- and low-molecular-weight HA used in the device is obtained by biofermentation and has not undergone chemical modification processes; this results in excellent tolerability of the product.

In addition, the HA chains with different molecular weight present in **PROFHILO® STRUCTURA**, thanks to a specific and patented treatment of the solution (***NAHYCO® Hybrid Technology)***, interact with each other, giving **PROFHILO® STRUCTURA** unique rheological properties that allow higher concentrations of HA to be administered at equal viscosity of the solution.

The formulation based on HA with different molecular weight contained in **PROFHILO® STRUCTURA** is based on the Hydrolift® Action system, the innovative approach aimed at combating the physiological decrease of HA in the skin, restoring hydration, elasticity and tone, synergistically associating deep hydration with the mechanical lifting action of the skin depression.

INTENDED USE

PROFHILO® STRUCTURA is indicated for adults of both sexes for a corrective/filling action of natural and induced skin depressions.

PROFHILO® STRUCTURA intervenes in the physiological process of the reduction of skin hydration, alteration of the elastic fibres and collagen of the dermis with loss of turgor and skin tone, for example in cases of excessive dehydration, weight loss and aging, with relative loss of endogenous HA.

The viscoelastic and moisturising properties of HA, combined with the possibility of maintaining such HA at adequate levels in the skin tissues, allow rehydrating the tissues and creating the optimal conditions to prevent and to promote the tissue remodelling with consequent corrective effect on damages, for example in the scarring of the skin.

Intradermal/subcutaneous administration of **PROFHILO® STRUCTURA** hence allows restoring the physiological quantity of HA in the treated tissues obtaining benefit for the skin.

IFU - PROFHILO® STRUCTURA – Launch 01.2024

INDICATIONS

PROFHILO® STRUCTURA is indicated for

- face treatment and for restoring adipose tissues
- in the dermal tissue repair process, in cases of acne scars

INTENDED POPULATION AND USERS

PROFHILO® STRUCTURA is indicated for adults of both sexes and is to be administered by intradermal/subcutaneous injection by qualified personnel only.

PROFHILO® STRUCTURA IS TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

COMPOSITION

PROFHILO® STRUCTURA has consisted by the prefilled syringe with 1 or 2 ml of solution, which contains:

SYRINGE VOLUME	1 ml	2 ml
FUNCTIONAL COMPONENT		
SODIUM HYALURONATE	22.500 mg (H-HA) + 22.500 mg (L-HA)	45.00 mg (H-HA) + 45.00 mg (L-HA)
OTHER COMPONENTS		
SODIUM CHLORIDE	6.500 mg	13.000 mg
SODIUM PHOSPHATE	0.205 mg	0.410 mg
WATER FOR INJECTION	q.s. 1.0 ml	q.s. 2.0 ml

POSOLOGY

It is advisable to do an initial cycle of two treatment sessions at 30-day intervals, if necessary followed by maintenance treatments every 4 months. For administration of PROFHILO® STRUCTURA in the subcutaneous tissues, it is advisable to evaluate a specific protocol based on the degree of patient ageing.

AVAILABLE KITS

PROFHILO® STRUCTURA is available in kits of 1 prefilled syringe in the following volumes:

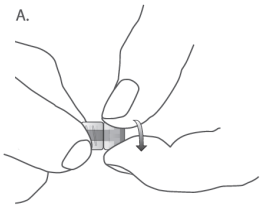
- 1 ml prefilled syringe (22.5 mg (H-HA) + 22.5 mg (L-HA) of hyaluronic acid sodium salt in 1 ml sodium chloride buffered saline solution)
- 2 ml prefilled syringe (45 mg (H-HA) + 45 mg (L-HA) of hyaluronic acid sodium salt in 2 ml sodium chloride buffered saline solution)

The content of the syringe is sterile and pyrogen-free.

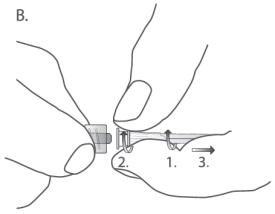
Prefilled syringe sterilized by moist heat.

INSTRUCTIONS FOR USE

- Carefully unscrew the syringe cap, firmly holding the Luer-lock closing neck between your fingers and being particularly careful to avoid contact with the opening (Figure A).



- Firmly holding the Luer-lock closing neck between your fingers, screw the needle/cannula tightly onto the closing neck of the syringe until you feel slight pressure so as to ensure an airtight seal and prevent liquid leakage during administration (Figure B).



- Inject **PROFHILO® STRUCTURA** at ambient temperature and in strict aseptic conditions.

Suggested injection technique:

The rheological properties of the gel give **PROFHILO® STRUCTURA** high diffusibility in the tissues surrounding the inoculation site.

PROFHILO® STRUCTURA can be applied through the most common injection techniques using both needle and cannula.

After the treatment:

After the treatment, the implant card must be filled in and provided to the patient; the implant card can be found in the first page of the instruction for use containing in the pack.

Instruction for completing the Implant card

Fill in the fields marked with the following symbols with the information indicated:

	Patient Name or patient ID
	Date of treatment

	Name and address of the implanting healthcare institution Name of medical practitioner**.**

WARNINGS

- The content of the prefilled syringe is sterile. The syringe is packed in a sealed blister pack.
- The outer surface of the syringe is not sterile.
- Do not use **PROFHILO® STRUCTURA** after the expiry date indicated on the package.
- Do not use **PROFHILO® STRUCTURA** if the packaging is open or damaged, because the sterility of the product could be compromised
- The injection site must be on healthy skin.
- Do not use in pregnant or breast-feeding women.
- Do not use in patients with autoimmune diseases.
- Do not inject intravascularly, into the muscles or tendons, or for breast enlargement.
- Do not mix with other products.
- Do not inject into areas where inflammatory processes are present.
- Do not resterilize. The device is intended for single use only.
- Do not reuse in order to prevent any risk of contamination.
- Store below 25°C and keep away from heat sources. Do not freeze.
- Once opened, PROFHILO® STRUCTURA must immediately be used and discarded after use.
- **PROFHILO® STRUCTURA** is indicated for adult patients.
- Keep out of the reach of children.
- Do not use **PROFHILO® STRUCTURA** in case of known hypersensitivity or allergies to the components of the product.
- Any air bubble present does not compromise the characteristics of the product.
- After injection and for the next 3-5 days, advise the patient to avoid exposure to UV rays and to protect the treated area with total protection sun creams.

PRECAUTIONS FOR USE

Do not mix **PROFHILO® STRUCTURA** with disinfectants such as quaternary ammonium salts or chlorhexidine as a precipitate may form.

INTERACTIONS

To date, in vitro studies have been conducted to identify any incompatibility and/or interactions between PROFHILO® STRUCTURA and Plasma-Rich Platelets (PRP). The results obtained show that PRP does not modify the rheological behaviour of sodium hyaluronate.
There are no known interactions between **PROFHILO® STRUCTURA** and other drugs/treatments.

Nonetheless, in case of therapies and/or taking medications in conjunction with the treatment, consult your doctor for more information.

SIDE EFFECTS

Extradermal infiltration of **PROFHILO® STRUCTURA** may locally cause undesirable effects.
During use of **PROFHILO® STRUCTURA**, symptoms such as pain, sensation of heat, itching, burning, reddening, ecchymosis, oedema or swelling may occur at the injection site. These secondary manifestations can be relieved by applying ice on the treated area. They generally disappear after a short period of time.
Physicians must ensure that patients notify them of any undesirable effects that occur after the treatment.
In the event of an incident, inform the manufacturer or the competent authority.

OVERDOSE

Follow the posology indicated and if you experience any side effects related to an overdose, contact your doctor or nearest hospital.

CONTRAINDICATIONS

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

Shelf-life: 36 months.
The expiry date indicates the maximum shelf-life of the medical device referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET

April 2022

DISPOSAL

Do not dispose of the product in the environment after use. Follow local regulations for disposal of the product.

To the following link it's possible to download the Summary of Safety and Clinical Performance:

https://www.ibsa.it/en/chi-siamo/summary-of-safety-and-clinical-performance.html
https://www.ibsa.it/en/chi-siamo/sscp-area-riservata.html

MANUFACTURER

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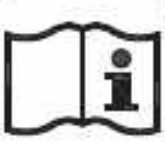
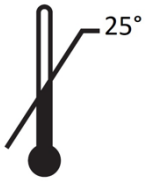
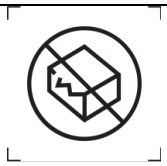
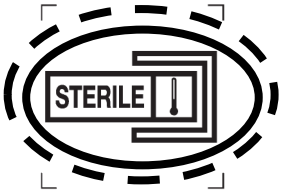
CE **0477**	 See the instructions for use	 Use by...	 Batch

 Single-use	 Storage temperature	 Sterilized by moist heat	 Do not resterilize
 Do not use if the package is damaged	 The medical device contains a sterile fluid path that has been sterilized by moist heat. Moreover indicates a single *sterile* barrier system with protective packaging outside	 Manufacturer	 Unique device identifier
 Medical Device	 Date of manufacture	 Caution ! Read the warnings carefully	