

PATIENT INFORMATION LEAFLET (PIL)

PROFHILO STRUCTURA® (phonetic pronunciation – Pro-filo Structura)

Active ingredient(s): *hyaluronic acid*

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This leaflet provides important information about using PROFHILO STRUCTURA®. **You should also speak to your doctor or nurse injector if you would like further information, or if you have any concerns or questions about having a PROFHILO STRUCTURA® treatment.**

1. Why am I having PROFHILO STRUCTURA®?

PROFHILO STRUCTURA® is a crystal-clear injectable gel composed of hyaluronic acid, a natural substance that already exists in the body and fall under the class of Facial injectables.

PROFHILO STRUCTURA® is injected into the skin with an ultrafine needle and allows rehydration of the tissues and creation of the optimal conditions to promote tissue remodelling.

The intended use of PROFHILO STRUCTURA® is:

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

2. What should I know before I have PROFHILO STRUCTURA®?

Warnings

PROFHILO STRUCTURA® must only be administered by a Medical Practitioner or a qualified nurse injector who operates under the supervision of a medical practitioner.

An initial cycle of two PROFHILO STRUCTURA® treatment sessions 30 days apart is recommended. This will be confirmed by your Medical Practitioner or Nurse Injector.

Do not use PROFHILO STRUCTURA®:

- If you are allergic to hyaluronic acid, or any of the ingredients listed at the end of this leaflet.
- if you have severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- if you suffer from bleeding disorders.
- at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present until the process has been controlled
- in concurrence with treatments such as laser resurfacing and medium deep skin-peeling.

PROFHILO STRUCTURA® must be used with needles. There is no specific risk arising from the interaction of PROFHILO STRUCTURA® with needles.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 5.

Pre-Treatment

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

Safety

Safety has not been established in the following:

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Other

- Highly allergic to hyaluronic acid, or any of the listed ingredients
- Prone to bleeding disorders

3. What if I am taking other medicines or having certain treatments?

Tell your doctor or injector if you are taking any other medicines, including any, vitamins or supplements. Likewise, please advise them of what skincare topical treatments and non-surgical cosmetic treatments you have had.

4. What should I do immediately after my PROFHILO STRUCTURA® treatment?

Things you should avoid

- Physical strain, headfirst movements and sports the day of and the day after treatment
- Sauna, steam bath, icy temperatures or UV radiation by the sun or a solarium for two weeks after the treatment
- Dental procedures for two weeks after the treatment
- Filler injections in the same area, microdermabrasion, chemical peel, IPL two weeks after the treatment
- Fractional resurfacing 4 weeks after the treatment
- If there's anything you're unsure about, consult your healthcare professional.

5. Are there any side effects?

All medical products can have side effects. If you do experience any side effects, most of them would be expected to be minor and temporary. However, some side effects may need medical attention.

Possible side effects	What to do
During the use of PROFHILO STRUCTURA®, 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, allergic reactions or unexpected adverse events, such as those arising from unintended injection into blood vessels, may occur after hyaluronic acid injections.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Healthcare Professional Reporting side effects

What to do
A notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration: www.tga.gov.au/reporting-problems Any serious incident occurring in relation to PROFHILO STRUCTURA® must be reported to the Manufacturer: IBSA Farmaceutici Italia Srl Via Martiri di Cefalonia 2, 26900, Lodi (Italy) Tel. +39 0371 6171 Fax. +39 0371 617244 https://www.ibsa.it/

Tell your doctor or nurse injector if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you have experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

6. Product details

This medicine is only available with a doctor's prescription.

What PROFHILO STRUCTURA® contains

Active ingredient (main ingredient)	4.5%- 22.5 mg high molecular weight hyaluronic acid sodium salt + 22.5 mg low molecular weight hyaluronic acid sodium salt /1 mL syringe 4.5%- 45 mg high molecular weight hyaluronic acid sodium salt + 45 mg low molecular weight hyaluronic acid sodium salt /2 mL syringe
Other Ingredients	Sodium Chloride, Sodium Phosphate and Water
Potential allergens	PROFHILO STRUCTURA® is non-animal based and free from animal protein. Allergy pretesting is not necessary

Do not take this medicine if you are allergic to any of these ingredients.

What PROFHILO STRUCTURA® looks like

PROFHILO STRUCTURA® is a crystal-clear injectable gel composed of hyaluronic acid, a natural substance that already exists in the body. PROFHILO STRUCTURA® is a medical device in the form of an injectable that is used by your doctor or nurse injector. It comes in a sealed box.

PROFHILO STRUCTURA® packaging included 1 pre-filled syringe.

Who distributes PROFHILO STRUCTURA®?

PROFHILO STRUCTURA® is distributed in Australia and New Zealand by Dermocosmetica. For more information, please contact:

e: info@dermocosmetica.com.au

t: + 61 (3) 9354 0898

a: 8, 14-16 Lens Street, Coburg North VIC 3058 Australia

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