

PATIENT INFORMATION LEAFLET (PIL)

PROFHILO®

(phonetic pronunciation – Pro-filo)

Active ingredient(s): *hyaluronic acid*

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This leaflet provides important information about using PROFHILO®. **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® treatment.**

1. Why am I having PROFHILO®?

PROFHILO® 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® is injected into the skin with an ultrafine needle to plump the skin to smooth away wrinkles and improve texture and skin quality. PROFHILO® is particularly indicated for the treatment of the Lower Face, Mid Face and Neck and other parts of the body.

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

Warnings

PROFHILO® 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® treatment sessions 30 days apart is recommended. This will be confirmed by your Medical Practitioner or Nurse Injector.

Do not use PROFHILO® 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.
- Defer use of PROFHILO® 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
- PROFHILO® must be used with needles. There is no specific Risk arising from the interaction of PROFHILO® with needles.
- PROFHILO® must not be used in concurrence with treatments such as laser resurfacing and medium deep skin-peeling.

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® 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® 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® 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.

The volumizing outcomes from PROFHILO have been shown to generally remain for up to 4 weeks after the first course of treatment, however please consult your Medical Practitioner to determine the best cycle of treatment.

The physical effects of PROFHILO can be shortened due to sun exposure (UV rays). After PROFHILO injection, protect the treated area from the sun using appropriate protection steps, including application of sunscreen.

No specific precautions are required to be applied near the end of the PROFHILO life-time, as by the product will predominantly be degraded within 4 weeks of injection.

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®, 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.	Speak to your doctor if you have any of these less serious side effects and they worry you.
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.	

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: Any serious incident occurring in relation to PROFHILO® 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® contains

Active ingredient (main ingredient)	3.2%- 16 mg high molecular weight hyaluronic acid sodium salt + 16 mg low molecular weight hyaluronic acid sodium salt /2 mL syringe
Other Ingredients	Sodium Chloride, Sodium Phosphate and Water
Potential allergens	PROFHILO® 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® looks like

PROFHILO® is a crystal-clear injectable gel composed of hyaluronic acid, a natural substance that already exists in the body. PROFHILO® 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® packaging included 1 pre-filled syringe with 2 needles 29G x ½" (0.33 x 12 mm).

Who distributes PROFHILO®?

PROFHILO® 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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