



Patient Information Leaflet

Profhilo®



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If you are considering having **Profhilo®** treatment, we recommend that you read the following information. This will help you to be fully prepared and know what questions to ask. We recommend that you check that the practitioner you choose is registered with a professional body. Although Profhilo® is classed as a medical device and does not require a prescription, we recommend that you choose a prescribing practitioner because if something does go wrong, you may need a prescription item to be able to correct this. Prior to treatment, you should have a face to face consultation with your treating practitioner and be offered a cooling off period before returning for treatment, so that you have time to consider your decision carefully based on the information you have been provided with.

What is Profhilo®?

Profhilo® consists of one of the highest concentrations of hyaluronic acid (HA) available in any aesthetic product. Hyaluronic acid is a naturally occurring substance, which is a major component of our skin and has a function in wound repair, hydration, and cell to cell communication. One of the main characteristics of hyaluronic acid is that it effectively binds water like a sponge. Profhilo® has been around since 2015, so it is a relatively new treatment, but has a low risk of complications. It comprises of a combination of high and low molecular weight hyaluronic acid (64mg of hyaluronic acid in a 2ml pre-filled syringe, 32mg of high molecular weight HA and 32mg of low molecular weight HA). Unlike most HA products that are cross-linked using chemical agents, Profhilo® is thermally stabilised. The thermal stabilisation process changes the character and behaviour of the HA and allows it to have a longer lasting effect. As there are no chemical cross-linking agents, Profhilo® contains pure hyaluronic acid.

Profhilo® is considered a bioremodeling agent as opposed to a dermal filler or biorevitaliser.

Profhilo® is often administered by injection with a small needle. It comes packaged in a box that contains sterile needles, product labels and a pre-loaded syringe that will be opened from its sterile packaging in front of you at the beginning of the treatment. The product label will include the name of the product, the batch number, and the expiry date. This should be documented on your treatment record and be given to you at your request.

Make sure you understand why Profhilo® may be suitable for you and alternative options.

What areas can be treated?

The most treated area is the face, often by using a specifically devised treatment technique of injecting 5 Bio Aesthetic Points (BAP) each side to maximise diffusion in the cheeks and lower face to achieve the best results, minimise discomfort and for safety by avoiding important structures and blood vessels.

Profhilo® can be used all over the body, but is particularly effective when treating the face, neck, and décolletage. Although less commonly performed, other possible treatment areas include:

- ✓ Hands
- ✓ Arms

- ✓ Knees
- ✓ Abdomen

- ✓ Buttocks



Ensure your practitioner is trained and experienced in treating your area of concern.

How does Profhilo® work?

Profhilo® is a revolutionary technology that delivers an anti-ageing treatment into the skin of your face, neck, and other areas of the body. The low molecular weight portion is responsible for hydration and stimulating the formation of new collagen and elastin within the skin whereas the high molecular weight component provides support and a scaffolding action. Due to thermal stabilisation, the pure hyaluronic acid remains in the skin for around 28 days, however the slow release of HA stimulates 4 different types of collagen and elastin for more lasting results. Despite its high HA content, it has a low inflammatory profile coupled with pro-healing properties backed by clinical studies.

Patients can expect increased firmness, elasticity, and an overall improved quality of the skin with the effects lasting about six months. This depends upon the degree of correction required, your age and lifestyle as well as the correct placement of the product by your practitioner.

Due to the revolutionary nature of Profhilo®, the whole face can be treated in around 15 minutes and bio-remodelling can be achieved in just two treatment sessions carried out four weeks apart. In order to maintain the results, additional treatments may be performed after 6-12 months.

Is it painful?

Profhilo®, unlike other dermal filler treatments, does not contain lidocaine, therefore a stinging or burning sensation can be experienced. A topical anaesthetic such as LMX4® or Emla™ may be used to provide

additional pain relief. This will be applied to the skin and left on the surface for 20-30 minutes to take effect.

Following the procedure, there may be some tenderness, which is expected, but you should not experience a significant degree of pain. If you are experiencing considerable pain after the treatment, you must contact your practitioner as this could indicate that you are developing a complication.

Is it safe?

Hyaluronic acid is a natural substance found in the skin and the substance itself is safe when it has been purchased from a reputable pharmacy or supplier. Counterfeit products carry a higher risk of adverse events, so it is important to seek a practitioner who can demonstrate the source of the product.

Profhilo® is composed of a highly pure grade of hyaluronic acid and with the absence of any additives, it is extremely biocompatible and has fewer documented adverse effects than traditional hyaluronic acid fillers.

Side-effects may be more likely due to the following factors:

- ✓ **Patient factors:** Condition of the skin, age, certain medical conditions, certain medications.
- ✓ **Practitioner factors:** Training, years of experience, number of procedures performed.
- ✓ **Premises factors:** Suitability of the premises.

Profhilo® has very few complications, however no treatment is without risk and these should be discussed during your consultation.

We recommend that treatments are performed in a suitable clinical environment.

Possible adverse effects include:

- ✓ **Pain:** You may experience some minor tenderness or discomfort post-treatment. If you do have more pain than expected, it is important to contact your treating practitioner immediately as this may indicate a complication, such as a vascular occlusion.
- ✓ **Redness:** This is normal and usually resolves quickly. If the treatment area becomes red a few days after treatment, particularly if heat is also present, this may indicate an infection and you need to contact your practitioner straight away.
- ✓ **Swelling:** Some swelling or oedema is normal after treatment and may be worse the following morning after the procedure. However, persistent swelling should be reported to your practitioner as there may be treatment to help relieve this.
- ✓ **Bruising:** As the procedure involves injections in the skin, bruising is a common finding. This can be anything from a small mark on the skin to extensive bruising which extends beyond the area treated and can take up to two weeks to resolve. Rarely, bruising can lead to permanent staining of the skin.
- ✓ **Infection:** Your treatment should be conducted in an appropriate clinical environment, your practitioner should adhere to infection control protocols and you should receive appropriate aftercare advice to lessen this risk. Infection often develops as a warm, red, swollen area over the area that has been injected a few days after your treatment. If this occurs, make sure you contact your practitioner for a review as soon as possible.

- ✓ **Tyndall Effect:** Rarely, hyaluronic acid may remain visible beneath the skin as a bluish or grey hue. Remedial treatment may be required to deal with this, and you should book a review appointment with your treating practitioner.
- ✓ **Herpes (Cold sores):** Treatment around the lip area can exacerbate an outbreak of herpes, which may be worse than a normal outbreak and may require treatment from your practitioner. The ACE Group World recommends that preventative medication may be required for certain treatments in people who are prone to cold sores. It is important that this is discussed as part of your medical history.
- ✓ **Lumps:** Following treatment, it is normal to have visible lumps at the injection sites. These dissipate over the next few hours but may be present for up to 48 hours and may be worse the morning after treatment. If you develop a lump several weeks or months after treatment, it is recommended to arrange a face to face review with your treating practitioner. Lumps may appear as soft swellings or as hard nodules. They sometimes occur following an acute illness, such as a dental or sinus infection, or with exposure to excessive sunlight.
- ✓ **Vascular Occlusion:** This is a rare, but serious, complication from dermal filler injections. In this situation, your blood supply may have been compromised by filler that has caused a blockage or obstruction of normal blood flow. If this is not correctly managed, the skin and tissue supplied by the blood vessel does not receive sufficient oxygen and can result in tissue loss, scarring and secondary infection. A vascular occlusion will normally cause severe pain, an irregular change in colour of the area treated and poor capillary refill (a test performed by your practitioner to see if the blood supply has been compromised). It will often appear immediately during treatment or soon afterwards and once this has been identified, your practitioner should have the necessary products at hand to effectively manage this.
- ✓ **Blindness:** This is an extremely rare and devastating complication that can occur with dermal filler treatments. There are certain areas of the face that pose a higher risk if they are injected, although it can occur from any facial dermal filler procedure. This should be discussed during your consultation with your practitioner, because if blindness occurs, it is likely to be permanent.
- ✓ **Stroke:** Another extremely rare, but documented complication of dermal fillers.

If you develop any unexpected side-effects after treatment, it is important to contact your practitioner for a review as soon as possible, as they may be able to offer some corrective treatment. Although your practitioner may contact you by telephone or video call initially or you may send your own photographs, this is no substitute for a face to face review to provide an accurate diagnosis.

Your practitioner should provide you with an out of hour's emergency number.

What does the procedure involve?

Prior to your treatment you should receive a full consultation, complete a medical questionnaire, and be offered a cooling off period to enable you to make an informed decision with full disclosure of the possible risks and side effects specific to you. You should also be given an indication of the cost of the treatment. Before you receive any treatment, you will be required to sign a consent form, this may be on paper or electronic, and be given the opportunity to ask any further questions. Photographs should be taken and kept as part of your medical record. These should not be used for any other purpose without your explicit permission.

Do not feel pressurised or coerced into having treatment at the same time as your consultation.

The practitioner will perform an examination of the area to determine the most appropriate treatment plan with you. The areas to be injected will usually be marked on the skin, using a pen or pencil, after it has been cleansed and disinfected. Your practitioner may measure the areas of your face to accurately identify the injection points. When treating the face, many practitioners will mark out 5 Bio Aesthetic Points on each side. It is important to have realistic expectations about what Profhilo® can achieve and this should be discussed with your practitioner prior to your treatment.

If a topical anaesthetic cream is to be used, this will be applied and removed after 20-40 minutes to allow it to take effect. The area to be treated will be cleaned, makeup removed if worn, and then disinfected. If a needle is used, you will experience several pin pricks or a scratching sensation and possibly a mild burning sensation as the product is injected. If a cannula is used, the practitioner may first inject a local anaesthetic to numb the insertion site, this itself can cause a burning or stinging sensation. Cannulas can create an odd pulling or tugging sensation as they are moved into place beneath the skin.



Treatment with Profhilo® will take around 15 minutes and following the procedure, your practitioner will clean the skin. It is likely that you will also be shown in a mirror the bumps that will be visible for a day or two. Once you and your practitioner are satisfied with the results of the treatment and you have had sufficient recovery time, you should be given the opportunity to book a follow up appointment, as you may need a second treatment in 4 weeks' time. You should also receive aftercare information either electronically or in paper form. Following treatment, you may notice an improvement within a few days although some patients may not see the benefit for up to 4 weeks after their second treatment. The skin should look more hydrated and have a healthy glow, fine lines and wrinkles should improve and the area should have a more youthful appearance. Even very aged skin should feel tighter, smoother and show an improvement in texture.

Am I suitable for treatment?

You may not be suitable for treatment if any of the following apply:

- ✓ Dermal fillers cannot be given to pregnant or breast-feeding women and is not recommended if you are actively trying to get pregnant or undergoing IVF.
- ✓ If you suffer from keloid scarring or have active skin conditions, such as acne or psoriasis.
- ✓ If you have certain medical conditions, such as diabetes, rheumatoid arthritis, autoimmune conditions, blood clotting disorders, cancer, immunosuppression (either medical or drug-related).
- ✓ If you are suffering from any skin infection in or near the treatment area, including cold sores.
- ✓ If you are suffering from any other infection, including dental, throat, ear, chest, or sinus infections.
- ✓ If you are unwell, including coughs and colds, on the day of treatment.
- ✓ If you are taking any medicines which affect bleeding, such as aspirin or warfarin.
- ✓ If you have had Roaccutane® or isotretinoin in the past 6 months.
- ✓ Certain allergies, including bee sting allergy.
- ✓ Recent facial surgery or other dermal fillers in the same area.
- ✓ Permanent implants, such as silicone implants in the face or pins and plates.

It is important to be honest about your medical history, previous surgery, previous or planned dental treatment and any medication taken so that you can have a safe and effective treatment.

Pre-treatment advice

- ✓ Avoid taking anti-inflammatories (such as aspirin, ibuprofen or naproxen) for 3 days prior to treatment (unless this has been prescribed by your doctor) as this increases the risk of bruising.
- ✓ Alcohol, fish oils, St. John's Wort, Gingko Biloba and Vitamin E should also be avoided for 3 days prior to treatment to lessen the risk of bruising.
- ✓ If you are prone to bruising, taking arnica orally for a few days prior to treatment may lessen the risk.
- ✓ If you are unwell on the day of your appointment, contact the practitioner to reschedule.
- ✓ Avoid sunbeds and tanning for 1 week before and after treatment.
- ✓ Ensure your practitioner is informed if there are any changes in your medical history or medication taken before receiving any treatment.
- ✓ Do not plan to have treatment within 2 weeks of an important social event or holiday as this may not allow enough time for side-effects, such as bruising to settle, or to have a review appointment.

Post-treatment advice

After treatment, most people can resume their normal daily activities. Immediately after treatment, there may be some redness, tenderness and swelling at the injection sites and there will likely be visible lumps at the injection sites. Bruising may be obvious immediately after treatment and may be quite pronounced.

Although there is little evidence, many practitioners advise the following:

- ✓ Do not apply make-up for 12 hours after treatment to reduce the risk of infection.
- ✓ Avoid saunas, swimming pools and sunbeds until the initial swelling and redness has settled.
- ✓ Try to avoid touching or rubbing the treated area until the following day, as you may affect the results of treatment or cause infection, unless otherwise advised by your treating practitioner.
- ✓ Massage of the area is not required; the product will diffuse naturally on its own.
- ✓ Avoid extremes of hot or cold and vigorous exercise until the initial swelling has resolved.
- ✓ If swelling persists, you may be advised to apply a cool pad to help remedy this.
- ✓ Contact your practitioner if you experience any unwanted side-effects.

Choosing your practitioner

Ensure you know the following information:



- ✓ Practitioner's full name
- ✓ Practitioner's profession (doctor, dentist, nurse, midwife, or pharmacist)
- ✓ Practitioner's contact details (address, telephone number, and email)
- ✓ An emergency contact number in case a complication occurs.

Practitioners should be registered with a professional body (General Medical Council, General Dental Council, Nursing and Midwifery Council or General Pharmaceutical Council) and you can check their current registration status online. Practitioners are accountable to these bodies and are legally required to have indemnity insurance in place for all the treatments they perform.

If you are not happy with your treatment outcome, you should attempt to resolve this with your treating practitioner in the first instance. If you need to see a different practitioner, you are entitled to receive a copy of your treatment record outlining the product used and areas and volumes injected, to have your concerns addressed safely. However, remedial treatment may not always be possible. Sometimes it may be necessary to allow time for the treatment to wear off.

ACE Group World was formed to help improve patient safety in medical aesthetics by producing evidence-based, peer-reviewed guidelines for the management of a wide variety of complications in non-surgical aesthetic practice. We also aim to provide help and advice for practitioners who encounter a problem.

ACE Group World hosts a forum for practitioners to share advice on the management of complications. It also provides an Emergency Helpline, email support and on-line educational modules for its members. The members also benefit from workshops, conferences, and a faculty of national and international experts.

ACE Group World works with aesthetic organisations, professional bodies, media, pharmaceutical companies, patient groups, insurers and regulatory bodies to provide professional advice and benefit for its members. Our mission is to improve regulation in the medical aesthetics sector and to provide ACE Group World Patient Information Leaflets to inform the public about what to expect and what questions to ask. We constantly strive to raise standards and improve patient safety.

Check your practitioner is a member of ACE Group World®:

www.acegroup.online

