

Patient Information Leaflet

Tear Trough Dermal Filler Injections





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If you are considering having a **tear trough** 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 dermal fillers are classed as a medical device and therefore do 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.

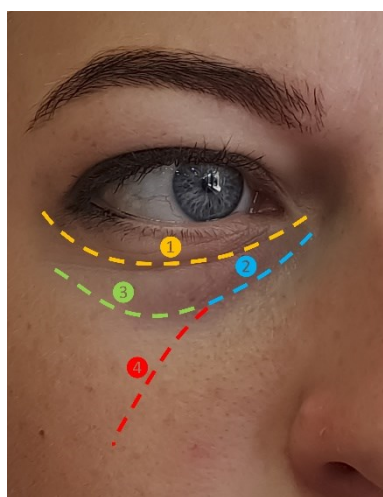
What are tear trough filler treatments?

Dermal filler injections are administered using either a small needle, a cannula or both. Dermal fillers usually come packaged in a box that contains sterile needles, product labels and a pre-loaded syringe that should 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 expiry date. This will be documented on your treatment records and should be given to you on request. The syringe will contain a clear gel like substance, which consists of a water-based carrier gel, hyaluronic acid, and may contain lidocaine, which is a local anaesthetic to make the treatment more comfortable. 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, which is why it is an effective tissue filler.

There are many different brands of filler available within the UK, but some have better safety profiles than others. Individual brands differ in the properties of the filler, including particle size, concentration and cross-linking which affects their resistance to degradation (how long the filler will last), elasticity and volumising effect. There are fillers available that have been manufactured specifically to treat the tear trough area which provides the optimum filler characteristics. An ideal tear trough filler should be only slightly hygroscopic (water absorbing) to lessen the risk of swelling and seeing the filler under the skin, as the skin is much thinner in this delicate area compared to other areas of the face. The viscosity and elasticity of the gel need to allow the filler to be flexible and more fluid to allow easy spreading in the tear trough. Some fillers also contain additional components (such as amino acids, antioxidants and vitamins) to help with revitalisation and repair and reduce the risk of swelling.

Make sure you ask what brand of dermal filler your practitioner will be using and why.

What is the tear trough?



The tear trough is a groove that lies between the lower eyelid at the inner corner of the eye and the upper cheek. A tear trough deformity (or hollow orbital rim) is not a deformity as such, but is the terminology often used by medical aesthetic practitioners to describe the deepening of this groove which occurs as a normal result of ageing or may be a hereditary feature. It is caused by changes in the bone, fat and skin.

If there is a prominent eye bag, which is caused by the sagging of the under eye fat pad, a tear trough treatment will not be the correct procedure and you should be advised to have a consultation with an oculoplastic surgeon to consider surgery (a lower lid blepharoplasty).

1 Orbital Rim 2 Tear trough 3 Palpebromalar groove 4 Mediojugal fold

Tear trough treatments are considered a more advanced procedure so ensure your practitioner is trained and experienced in this area.

How does it work?

During normal ageing, the fat compartments of the face lose volume and the ligaments holding them in place become weaker leading to a sagging appearance. When hyaluronic acid fillers are injected, they boost the skin's volume, so the area becomes revitalised and volumised. By placing the dermal filler in specific anatomical positions, this can also create a lifting effect. In the tear trough area, a less hydrophilic filler should be used to prevent the risk of creating too much volume and unsightly bulging.

Tear trough dermal fillers are injected using a small needle, a cannula or both and creates an instant filling out effect. Most syringes contain 1ml of hyaluronic acid and generally it is not recommended to inject more than one syringe of filler to treat both sides in one treatment session. If additional correction is needed, this can be performed at a later treatment session which should be discussed during your consultation. The results of a tear trough treatment will often last for approximately 12 months.

Is it painful?

Most dermal filler injections contain a small amount of lidocaine, which is a local anaesthetic to help reduce any pain experienced during the procedure. Even with the addition of local anaesthetic, it is not a pain free

treatment and it will depend on the injection technique, whether a cannula or needle is used and the individual's pain tolerance. In some circumstances, 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 20-40 minutes to take effect.

Although the skin in the tear trough is more delicate, any discomfort experienced during treatment is like other areas of the face. Most people will close their eyes during treatment, but it is important not to screw your eyes up as this may lead to more discomfort and may affect the results.

Once the anaesthetic has worn off, 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 naturally occurring substance present in the skin and the product itself is considered very safe when it has been purchased from a reputable pharmacy or supplier. Counterfeit products have been found in general circulation which do carry a much higher risk of adverse events, so it is important to seek a practitioner who can demonstrate the source of the product.

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.

We recommend that treatments are only 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 (oedema) is normal after treatment and may be worse the following morning. The tear trough is more prone to swelling than other areas of the face and if you are prone to swelling in this area, you are not likely to be a good candidate to have this procedure. 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 2 weeks to resolve. Rarely, bruising can lead to permanent staining of the skin. Due to the anatomy and vascularity in the tear trough region, this area is more prone to bruising and treatment may result in a black eye.
- ✓ **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.

- ✓ **Lumps:** Lumps may be present immediately after treatment due to product misplacement or migration of the product or may appear several weeks or months later in some cases. 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. If you develop a lump, it is recommended to arrange a face to face review with your treating practitioner.
- ✓ **Herpes (Cold sores):** An exacerbation of cold sores can occur with any facial injections but is rare if you are just having your tear trough area treated.
- ✓ **Vascular Occlusion:** This is a rare but serious complication from dermal filler injections. In this situation, your blood supply has 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 infections. A vascular occlusion will normally cause severe pain, an irregular change in colour of the area treated and poor capillary refill (a test that will be 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 resources to reverse 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 and has arisen following tear trough treatments. 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 be given a full consultation, complete a medical questionnaire and be allowed 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. They will advise on what product and how much will be required to perform the treatment as well as whether they will be using a needle, a cannula or both. It is important to have realistic expectations about what dermal fillers to the tear trough can accomplish, as often the area is improved rather than achieving a full correction.

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 of the tear trough area will often take between 15 to 30 minutes to perform. Following your procedure, the practitioner may massage the area and then clean the skin. Some practitioners might apply a cream post-treatment. Once you and the practitioner are satisfied with the results of the treatment and you have been given sufficient recovery time, you should be given the opportunity to book a follow up appointment and receive aftercare information either in paper form or electronically.



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 lidocaine or 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.

Tear trough treatment may also not be suitable if:

- ✓ The cause of the problem is predominantly due to pigmentation and dark circles.
- ✓ If you have prominent eye bags in the lower eyelids.
- ✓ If you are prone to puffiness in the under-eye area or have poor lymphatic drainage in the area.
- ✓ If you have excessive skin laxity in the under-eye area.

Your practitioner will perform an examination during your consultation and advise you if any of the above apply and may suggest alternative treatment for these problems.

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, 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, Ginkgo Biloba, garlic 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.
- ✓ Be prepared for some bruising and swelling, this is more common following tear trough treatment.

Post-treatment advice

After treatment, most people can resume their normal daily activities. Immediately afterwards, there may be some redness, tenderness and swelling 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 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 practitioner.
- ✓ 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.

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