Patient Information Leaflet

Ellansé® Dermal Filler Injections

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If you are considering having treatment with **Ellansé® dermal filler**, 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 Ellansé® is classed as a medical device and therefore 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. 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 Ellansé® dermal filler injections?

Dermal fillers are natural or synthetic gels that are injected into the skin to volumise, lift and improve the appearance of lines. Most dermal fillers are completely biodegradable and have a temporary effect. There are many different brands of filler within the UK and the majority are comprised of hyaluronic acid.

Ellansé® is not a hyaluronic acid dermal filler, it is made up of an aqueous carboxymethylcellulose (CMC) gel containing polycaprolactone microspheres and belongs to the bio-stimulating class of dermal fillers. Unlike hyaluronic acid dermal fillers which are colourless gels, Ellansé® is white in colour. Polycaprolactone is a biodegradable material which has been used extensively in medicine as an injectable drug delivery system as an implantable biomaterial.

Ellansé® is injected in much the same way as most hyaluronic acid fillers, but unlike hyaluronic acid fillers, it **cannot be dissolved with hyaluronidase**. Ellansé® is comprised of 70% CMC gel and 30% polycaprolactone.

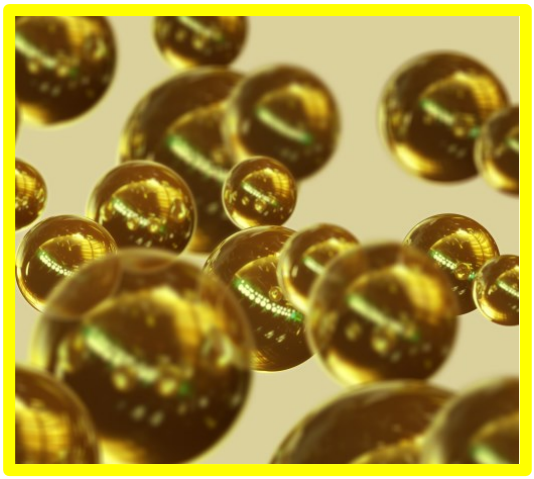
Ellansé® dermal filler injections are administered with a small needle, a cannula or both and is available in a syringe size of 1ml. Unlike many dermal fillers, Ellansé® does not contain lidocaine, a local anaesthetic

agent, but your practitioner may add this to the syringe. Although this is widely practised, this is an off-license indication and not endorsed by the manufacturer. Each pre-loaded syringe is contained within a sterilised silver foil pouch and packaged in a box with a traceability label showing the date of manufacture, the lot number, and the expiry date. This will be documented on your treatment records and should be provided to you on request. Ensure that the foil packet containing the syringe is opened in front of you.

There are four preparations of Ellansé® S|M|L|E. Each has the same amount of CMC gel and polycaprolactone spheres, the only difference is the amount of time the filler lasts after it has been injected. This is down to the tunable longevity or the time it takes for the spheres to be degraded. All products in the Ellansé® range are injected in the same way, using the same techniques, and can be placed at the same sites. The expected duration of effect for each product is:

Ellansé®S – 1 year Ellansé®M – 2 years Ellansé® L – 3 years Ellansé® E – 4 years

Bio-stimulation



During an Ellansé® dermal filler treatment, an immediate improvement in volume and lifting is obtained from the CMC gel, in much the same way as the hyaluronic acid fillers. The difference with Ellansé®, being a bio-stimulating filler, is that the polycaprolactone microspheres encourage the body to produce new collagen. The formation of collagen around the microspheres gives a longer lasting result. The microspheres are broken down naturally by the body over time and results with Ellansé® will last from between 1 and 4 years depending on which product is used. The CMC gel will be absorbed by the body over a shorter time, around 8-12 weeks, by which time the body has started to replace it with its own collagen. The ability for an individual to produce collagen varies, and may be influenced by lifestyle, age, and metabolism.

What areas can be treated?

Ellansé® can be used in most areas of the face and some areas of the body. However, it is not recommended to use Ellansé® to treat the lips or the tear trough (under eye area). Technique is important and practitioners generally classify treatments as either basic, intermediate, or advanced.

Commonly treated areas include:

- ✓ Nasolabial folds (nose to mouth lines)
- ✓ Upper and lower cheeks
- ✓ Oral commissures (corners of the mouth)
- ✓ Marionette lines (lines below the mouth corners)
- ✓ Jaw line
- ✓ Jowls
- ✓ Chin
- ✓ Nose reshaping
- ✓ Temples
- ✓ Eyebrows
- ✓ Backs of hands

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

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. Ellansé® can be injected in specific anatomical positions to create volume and a lifting effect, so the area becomes revitalised and volumised. Adding volume helps to address issues such as volume loss, laxity and sagging of the skin, having a positive effect on lines and wrinkles. They can also be injected directly beneath lines to help soften and improve them.

Your practitioner will discuss your treatment plan and highlight any specific risks based on the treatment area and your medical history. Often more than one syringe will be required to produce the desired result, and this may be performed at the same time or at a later treatment session and should be discussed during your consultation.

Is it painful?

Many practitioners who use Ellansé® will add lidocaine to the syringe, 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. If lidocaine is not added, it may be more uncomfortable.

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.

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?

Ellansé® has an excellent safety record, has FDA approval and is CE marked. 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, clinical environment, infection control.

There are certain risks from dermal filler treatments which should be discussed during your consultation.

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

Possible adverse effects include:

- ✓ **Pain:** You may experience some minor tenderness or discomfort post-treatment, but this should not be significant. 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 you may need 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 setting. The 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.
- ✓ **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 recommend 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:** 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 high exposure to excessive sunlight. If you develop a lump, it is recommended to arrange a face to face review with your treating practitioner.
- ✓ **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. As you are unable to dissolve Ellansé®, the management of this rare complication is more difficult with this filler.
- ✓ **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 be given 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. They will advise on how much product 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 Ellansé® treatments can achieve.

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.

Depending on the treatment area(s) and the amount of Ellansé®, treatment time will likely be between 15 to 30 minutes. 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:

- ✓ Ellansé® 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, such as lidocaine.
- ✓ Recent facial surgery or other dermal fillers in the same area.
- ✓ Permanent implants, such as silicone implants in the face or pins and plates.
- ✓ Previous rhinoplasty if considering dermal fillers in the nose.

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, 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.

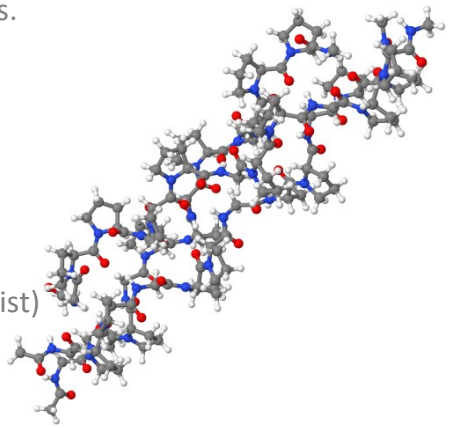
Post-treatment advice

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. 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 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.

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

www.acegroup.online