# ELLANSE

## The regenerative volumising filler

Model is not an actual patient.



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# Safely treating the true cause of facial ageing<sup>1</sup>

While your patients might want a quick fix, it isn't often the best way to achieve natural-looking and long-lasting results. But thanks to Ellansé, you can now offer them both; high quality, instant results and long-lasting powerful benefits.

A UNIQUE COMPOSITION: PCL AND CMC1



Ellansé goes beyond simply correcting superficial lines and folds. A unique dual-action dermal filler, it also works deep under the skin to treat the real causes of facial ageing by stimulating the body's production of natural collagen.

#### THE SCIENCE BEHIND THE STIMULATION

Combining smooth PCL microspheres with a CMC-based carrier gel<sup>2</sup>, Ellansé gets to work immediately, filling the areas affected by volume loss. Then, the microspheres degrade over time, leaving behind collagen structures that steadily rebuild and reshape facial contours to restore the skin's youthful infrastructure.



PCL chains within the microsphere

# Innovation for safety and optimal results<sup>1</sup>

#### SAFETY

From its launch in 2009, Ellansé's excellent safety profile has been continuously reported, not only in clinical trials and vigilance surveys but also by clinical experts in daily practice.<sup>3</sup>

In a review of adverse events from launch to August 2022, the adverse event rate was 0.0462% - or 1 event in 2,165 syringes.<sup>4</sup>

#### **ADVERSE EVENT RATE BY TYPE:**<sup>4</sup>

0.0032% 0.0207% NODULES / LUMPS HARDNESS / INDURATION 0.0008% 0.0121% INFECTION SWELLING 0.0031% 0.0010% **BRUISING / HAEMATOMA** INFLAMMATION

## A UNIQUE AND SAFE COMPOSITION



PCL is biodegradable and bioresorbable, naturally hydrolysed by the body into CO<sub>2</sub> and H<sub>2</sub>O.<sup>5</sup>



CMC is a widely-used component classified as generally recognised as safe (GRAS).<sup>5</sup>

### Long-lasting results for sustained effectiveness

Ellansé is available in two options: S and M with results lasting for 18 months and 24 months respectively,\* distinguished only by the initial polymer chain length of the PCL.

ELLANSÉ 18 MONTHS\*

**ELLANSÉ** 24 MONTHS\*

Treatment effects have variable duration dependant on the variant used, practitioner injection technique, patient lifestyle and metabolic rate.



**6** ELLANSÉ PRACTITIONER GUIDE

# Innovation for safety and optimal results<sup>1</sup>

90% of patients, having undergone an Ellansé S

**100%** of patients, having undergone an Ellansé M

High efficacy of Ellansé-S and Ellansé-M in nasolabial fold treatment with high safety over a 2 year period<sup>6</sup>

Investigator Evaluated Global Aesthetic Improvement Scale (GAIS)



A clinical trial by Moers-Carpi and Sherwood (2013) assessed the effectiveness of Ellansé-S (n=10) and Ellansé-M (n=30) for the correction of moderate to severe nasolabial folds using GAIS at 3, 6, 9, 12, 18 and 24 months post-treatment.



## Ellansé M offers immediate and sustained performance<sup>7</sup>

• Efficacy increases notably from 1 to 3 months • Results are maintained for up to 24 months



A clinical trial by Bae et al. (2016) evaluated the safety and efficacy of forehead augmentation with Ellansé-M in combination with botulinum toxin Type A (n=58). Efficacy was assessed using physician scores from the GAIS at 1, 3, 6, 12 and 24 months post-treatment.

## Proven Neocollagenesis for regenerative results

2013: 21 months post-injection (rabbit), Type I collagen confirms stable environment and long-term efficacy.<sup>8</sup>



COLLAGEN

2015: 13 months post-injection, confirmed collagen production in the human body. PCL microspheres were surrounded with collagen deposition and a mild fibroblastic and histiocytic tissue response (Martin's Trichrome staining,

Actual patient. Individual results may vary.

a collagen staining).9

Mean GAIS score over a 24-month period. The scores increased notably from 1 to 3 months, and the scores were well maintained for up to 24 months.

#### MEAN GAIS SCORES PHYSICIAN EVALUATION

1 month	3 month	6 month	12 month	24 month
2.14 ± 0.95	2.38 ± 0.77	$2.50 \pm 0.76$	$2.45 \pm 0.52$	2.33 ± 0.50

#### Global Aesthetic Improvement Scale (GAIS)

3 = very much improved | 2 = much improved

1 = improved | 0 = no change | -1 = worse

## Beyond Hyaluronic Acid (HA) and Collagen Stimulators

## Ellansé versus Hyaluronic Acid Fillers

Ellansé offers clear advantages over the NASHA-based dermal filler in terms of performance, durability and efficacy.

A split-face clinical study by Galadari et al. (2015) evaluated the safety and efficacy of Ellansé S with the HA dermal filler, Perlane, when used to treat moderate to severe nasolabial folds (n=40). Efficacy was compared using the mean wrinkle severity rating score (WSRS).

- Statistically superior to an HA dermal filler, Ellansé outperforms non-animal stabilised hyaluronic acid (NASHA)based dermal filler in both effectiveness and longevity.<sup>10</sup>
- Compared to the NASHA-based dermal filler effect. results show that Ellansé achieved the optimal result with a 17% lower injection volume.<sup>10</sup>
- · Ellansé was shown to build greater structural support and volumisation, with significantly higher elasticity (G' of 1,000 Pa) than the NASHA dermal filler.<sup>7</sup>
- After neocollagenesis, Ellansé provides an elastic modulus almost equal to that of the dermis and is cosmetically more favourable than an HA dermal filler.<sup>7</sup>

## Fllansé versus **Collagen Stimulators**

#### IMMEDIATE AND SUSTAINED PERFORMANCE

- Collagen stimulation induces long-term volumising capacity, for lasting, natural-looking results from a minimum of 18 months to 24 months.\*
- Immediate results compared to Poly-L-Lactic Acid (PLLA)-based filler.
- · Improved stability and duration compared to Calcium Hydroxylapatite (CaHA)-based filler.

#### SMOOTHER, MORE SPHERICAL MICROSPHERES,<sup>11-15</sup>

Ellansé is composed of smooth, spherical PCL particles with a diameter of 25-50µm. Since rough surfaces and irregular-shaped particles can cause adverse reactions (such as nodules and decreased collagen deposition), it's been specifically designed for optimum compatibility with the body.



Ellansé microspheres Circularity (mean) †0.997



SUMMARY

Smooth surface compared to PLLA-based filler.

Α

Improved, long-term volume and control of mass loss compared to CaHA-based filler.

\* Treatment effects have variable duration dependant on the variant used, practitioner injection technique, patient lifestyle and metabolic rate. \*\* Expected duration of action based on three sessions. † Roundness calculated by Flow Particle Image Analyser (FPIA).

B





picture (SEM)

#### SMOOTH



Scanning Electron Microscope

#### SPHERICAL MICROPARTICLES



Light microscopy picture

#### HIGH QUALITY SCAFFOLD



Light microscopy: Histology 2-weeks post-injection

DR	POLYMER/ MINERAL <sup>°</sup>	SIZE	SHAPE	SURFACE	DURATION
	PCL	25 - 50 µm	Spherical	Smooth	From 18-24 months* <sup>16</sup>
	CaHA≬	25 - 45 µm	Generally spherical	Smooth	Over 12 months <sup>17</sup>
	PLLA	40 - 63 µm	Irregular	Irregular	25 months** <sup>18</sup>





Radiesse microspheres Circularity (mean) <sup>+</sup>0.994



Sculptra microspheres Circularity (mean) †0.682



Longer-lasting results compared to PLLA and CaHA-based fillers with no top-up sessions required.



# Ellansé for volume restoration and rejuvenation

Ellansé comes with the added benefit of improving the skin's quality as evidenced clinically and via various quantitative parameters.<sup>19, 20</sup>

In cases, with results being more significant and longer lasting than other available tested dermal fillers.<sup>20</sup>

So, Ellansé not only immediately corrects lines and folds and gradually restores facial contours, it also enhances the skin's density, firmness, tonicity and texture from within.<sup>20</sup>

## Ellansé versus Baseline<sup>20</sup>

A clinical trial was conducted to assess the effect of Ellansé (n=24) on skin quality parameters at 3, 6, 9, 12, 18 and 24 months post-treatment in the mid-face.

Echographic analysis revealed the improvement of skin density was statistically significant at all time points in comparison with the baseline following treatment with Ellansé.



Ellansé also enhances a number of other skin biomechanical parameters; skin firmness, tonicity and smoothness were statistically significantly improved, in comparison with the baseline.



Actual patient. Individual results may vary.

Although Ellansé was injected in the subdermis, subject echographs clearly display a substantial increase in tissue density in the dermis.



BASELINE

**18 MONTHS POST** 



## Where to use Ellansé?

Fllansé is indicated for subdermal (subcutaneous fat/hypodermis) injections.

Experts recommend the injection modalities per region (upper, mid and lower-face) and per area.<sup>21</sup>



### **DID YOU KNOW?**

Ellansé can also be injected into the nose and chin, offering a minimally-invasive alternative for reshaping and contouring.

Ellansé's characteristics make it easy to shape and mould, allowing treated areas to be defined more precisely and naturally.

(A) Epidermis (B) Dermis (C) Subcutaneous fat/hypodermis (D) Supraperiosteal layer (E) Ellansé



## Which areas can Ellansé treat?

#### UPPER-FACE

- A. Forehead
- **B**. Temples
- C. Brow area

#### MID-FACE

- D. Nose reshaping
- E. Cheek augmentation
- F. Nasolabial folds

#### LOWER-FACE

- G. Oral commissures
- H. Marionette lines
- I. Chin definition
- J. Jawline

# Audrea

AGE 45 2 WEEKS AFTER ELLANSÉ

#### TREATMENT – MID-FACE

Piriform fossa Bolus 0.2 ml left and right

Zygoma Retrograde fanning 1 ml left and right

Cheeks Retrograde fanning 0.6 ml left and right

#### TREATMENT – LOWER-FACE

Jowl Retrograde fanning 0.3 ml left and right Nasolabial folds Retrograde fanning 0.3 ml left and right

#### **BEFORE ELLANSÉ**

- Loss of volume on the mid-face
- Deep nasolabial folds
- Sagging face

#### AFTER ELLANSÉ

- Volume replenished on cheeks
- Softened nasolabial folds
- Overall better facial definition







The procedure featured was performed by Dr. Victoria Manning in London, UK, using Ellansé M. Actual patient. Individual results may vary.



#### 2 WEEKS AFTER ELLANSÉ





AGE 40 3 MONTHS AFTER ELLANSÉ

#### TREATMENT – MID-FACE

Piriform fossa Bolus 0.15 ml left and right

Zygoma Retrograde fanning 0.9 ml left and right

Preauricular area Retrograde fanning 0.3 ml left and right

#### TREATMENT – LOWER-FACE

Marionette lines Retrograde fanning 0.3 ml left and right Nasolabial folds

Retrograde fanning 0.3 ml left and right

#### **BEFORE ELLANSÉ**

- Loss of volume on the mid and lower-face
- Noticeable facial lines

#### AFTER ELLANSÉ

- Volume replenished on cheeks
- Softened nasolabial folds and marionette lines









The procedure featured was performed by Dr. Victoria Manning in London, UK, using Ellansé M. Actual patient. Individual results may vary.





**3 MONTHS AFTER ELLANSÉ** 

# Micheal

AGE 57 3 MONTHS AFTER ELLANSÉ

#### TREATMENT – MID-FACE

Piriform fossa Bolus 0.15 ml left and right

Cheeks Retrograde fanning 0.7 ml left and right

#### TREATMENT – LOWER-FACE

Marionette lines Retrograde fanning 0.8 ml left and right

Jawline Retrograde fanning 0.8 ml left and right

#### **BEFORE ELLANSÉ**

- Loss of volume on the mid-face
- Noticeable facial lines
- Uncontoured jawline

#### AFTER ELLANSÉ

- Volume replenished on cheeks
- Softened marionette lines
- Redefined chin







2 WEEKS AFTER ELLANSÉ



The procedure featured was performed by Dr. Victoria Manning in London, UK, using Ellansé M. Actual patient. Individual results may vary.



#### **3 MONTHS AFTER ELLANSÉ**



# Paul

AGE 48 3 MONTHS AFTER ELLANSÉ

#### TREATMENT – MID-FACE

Cheeks Retrograde fanning 0.4 ml left and right

#### TREATMENT – LOWER-FACE

Mandibular angle Bolus 0.2 ml left and right

Jawline Retrograde fanning 0.8 ml left and right

Mental crease Retrograde fanning 1.2 ml

Chin Bolus 1.2 ml

#### **BEFORE ELLANSÉ**

- Loss of volume on the mid and lower-face
- Undefined and uncontoured jawline
- Receding chin

#### AFTER ELLANSÉ

- Volume replenished on cheeks
- Jawline definition recreated
- Chin projection created









The procedure featured was performed by Dr. Victoria Manning in London, UK, using Ellansé M. Actual patient. Individual results may vary.



#### **3 MONTHS AFTER ELLANSÉ**





# High patient satisfaction

Patient satisfaction rated at 24 months following treatment with Ellansé S and Ellansé M.



A year after Ellansé it felt fantastic to be told by friends that I looked much younger than my true age.

MARIA 12 MONTHS AFTER ELLANSÉ



PATIENT **TESTIMONIES** 

# Ellansé by Sinclair. Transforming customer confidence.

Ellansé is part of Sinclair's global portfolio. Founded in 1977, Sinclair delivers a unique range of scientifically-advanced, high-margin aesthetic products and services made exclusively for a worldwide industry of high-skilled clinicians.

But beautiful, lasting results aren't down to products alone. It's the combination of science and talent that creates the kind of transformations that can change lives for the better.

It's this understanding that makes Sinclair's approach to high standards unwavering. That's why we place as much emphasis on supporting our exceptional clinicians through training, as we do on our product portfolio.

### WITH ELLANSÉ YOU'LL HAVE ACCESS TO:

#### Sinclair College

Sinclair's educational arm, providing guality training and education, through collaboration and insight from worldwide experts. Unlock specialist Ellansé training from the Sinclair College platform; available on desktop and via My E-College App.

Scan the QR code using a mobile device.

Not a member yet?



#### Ongoing practice support

A dedicated Sales Representative, as well as free marketing materials via the Sinclair Portal. A free platform from where you can download our product brochures, aftercare leaflets and waiting room videos.

#### Ellansé Expert's Guide

A book presenting a novel approach to the art of injecting, detailing all you need to know about Ellansé.

From the latest detail on facial anatomy and the ageing process to best practice guidance from leading physicians and a discussion on the latest technologies to deliver Augmented Reality assets that bring the Ellansé injection techniques to life.





# Ellansé publication listing

A novel dermal filler and promising new device with immediate aesthetic correction and sustained results due to the formation of new collagen. The PCL microspheres in the filler trigger a natural response within the human body to stimulate neocollagenesis.

Gritzalas K. Preliminary results in using a new dermal filler based on poly-caprolactone. Eur J Aesth Med Dermatol. 2011;1:22-26.

Mixing lidocaine into the PCL-based dermal filler can be safely performed without causing harmful changes to the physical properties of the original dermal filler. Adding up to 0.3% of the anaesthetic agent lidocaine will not substantially affect the filler's characteristics, confirming the usability of this mixture in clinical practice.

De Melo F, Marijnissen-Hofsté J. Investigation of physical properties of a polycaprolactone dermal filler when mixed with lidocaine and lidocaine/ epinephrine. Dermatol Ther. 2012;2:13-22.

Ellansé is safe, well tolerated and effective for hand rejuvenation with high patient satisfaction and retention rates. Ellansé provides an immediate effect and offers a good choice based on its longevity.

Figueiredo VM. A five-patient prospective pilot study of a polycaprolactone based dermal filler for hand rejuvenation. J Cosmet Dermatol. 2013;12:73-77.

Ellansé-S and Ellansé-M are safe and have sustained efficacy and high patient satisfaction results over 24 months. Ellansé is a unique option for patients seeking longer lasting but non-permanent results.

Moers-Carpi MM, Sherwood S. Polycaprolactone for the correction of nasolabial folds: a 24-month, prospective, randomized, controlled clinical trial. Dermatol Surg. 2013;39 (3 Pt 1):457-63.

The PCL microspheres of Ellansé-M are still present 21 months post-injection. The PCL microspheres are embedded in a collagen scaffold of primarily type-1 collagen fibres.

Nicolau P, Marijnissen-Hofsté J. Neocollagenesis after injection of a polycaprolactone based dermal filler in a rabbit. Eur.J.Aesth Medicine and Dermatology. 2013;3:19-26. PCL-based dermal fillers offer advantages over the NASHA-based dermal fillers, in terms of both cosmetic longevity and efficiency. 17% less injection volume was required with Ellansé to reach optimal cosmetic effects compared to the NASHA dermal filler.

Galadari H, et al. A randomised, prospective, blinded, split-face, single-centre study comparing polycaprolactone to hyaluronic acid for treatment of nasolabial folds. J Cosmet Dermatol. 2015;14(1):27-32.

13 months after an Ellansé-M injection, PCL microspheres were surrounded by collagen deposition and a mild fibroblastic and histiocytic tissue response was seen. This confirms that PCL particles are maintained in their original state at least 13 months post-injection in human tissue.

Kim JA, Van Abel D. Neocollagenesis in human tissue injected with a polycaprolactone-based dermal filler. J Cosmet Laser Ther. 2015;17(2):99-101.

Ellansé shows advantages over an HA dermal filler when applied to the forehead. Ellansé has significantly higher elasticity (G') compared to the HA dermal filler and the non-crosslinked CMC molecules make it smoother and easier to inject. These neocollagenesis benefits are long term and the natural looking results last for at least 24 months.

Bae B, et al. Safety and long-term efficacy of forehead contouring with a polycaprolactone-based dermal filler. Dermatol Surg. 2016;42(11):1256-60.

A multinational, multidisciplinary group of experts, plastic surgeons and dermatologists have developed recommendations on the injection techniques of Ellansé. These recommendations provide a guideline for physicians who wish to perform safe and efficacious treatment for volume augmentation and rejuvenation of the face and hands.

De Melo F et al. Recommendations for volume augmentation and rejuvenation of the face and hands with the new generation polycaprolactone-based collagen stimulator (Ellansé<sup>®</sup>). Clinical, Cosmetic and Investigational Dermatology 2017:10 431-440.

A 46-year-old Asian woman was treated with Ellansé to restore facial volume loss. Facial images after Ellansé treatment revealed a more reverse triangular shaped and in proportion rejuvenated face coupled with the improvement of a downward shift of soft tissue

Lin SL. Polycaprolactone facial volume restoration of a 46-year-old Asian woman: A case report. J Cosmet Dermatol. 2018; 1-5.



## References

#### 1. Data on file.

- 2. Whitepaper W113.05.
- Christen MO, Vercesi.F. Polycaprolactone: Or How a Well-Known and Futuristic Polymer Has Become an Innovative Collagen-Stimulator in Aesthetics. Clin Cosmet and Investig Dermatol 2020; 12:1-18.
- 4. Ellansé post market surveillance report, 2022.
- 5. Christen MO Ellansé safety report. 2016.
- Moers-Carpi MM, Sherwood S. Polycaprolactone for the correction of nasolabial folds: a 24-month, prospective, randomized, controlled clinical trial. Dermatol Surg. 2013;39 (3 Pt 1):457-63.
- Bae B, et al. Safety and long-term efficacy of forehead contouring with a polycaprolactone-based dermal filler. Dermatol Surg. 2016;42(11):1256-60.
- Nicolau P, Marijnissen-Hofsté J. Neocollagenesis after injection of a polycaprolactone based dermal filler in a rabbit. Eur.J.Aesth Medicine and Dermatology. 2013;3:19-26.
- Kim JA, Van Abel D. Neocollagenesis in human tissue injected with a polycaprolactone-based dermal filler. J Cosmet Laser Ther. 2015;17(2):99-101.
- Galadari H, et al. A randomised, prospective, blinded, split-face, single-centre study comparing polycaprolactone to hyaluronic acid for treatment of nasolabial folds. J Cosmet Dermatol. 2015;14(1): 27-32.
- 11. Laeschke K. Biocompatibility of microparticles into soft tissue fillers. Semin Cutan Med Surg. 2004; 23(4):214-217.
- Morhenn VB et al. Phagocytosis of different particulate dermal filler substances by human macrophages and skin cells. Dermatol Surg. 2002;28(6):484-490.

- Anderson JM. Mechanism of inflammation and infection with implanted devices. Cardiovasc Pathol. 1993;2:33S-41S.
- Matlage BF et al. Tissue response to implanted polymers: The significance of sample shape. J Biomed Meter Res. 1976;10:391-397.
- Nicolau PJ. Long-Lasting and permanent fillers: Biomaterials influence over host response. Plast Reconstr Surg. 2007; 119:2271-2286.
- 16. Ellansé Instruction for Use. Sinclair IS Pharma Corporate. 2016.
- 17. Radiesse instruction for Use. Merz Aesthetics. 2016.
- 18. Sculptra Instruction for Use. Galderma. 2016.
- Moers-Carpi MM, Christen MO, Delmar H, Brun P, Bodokh I, Kestemont P. European Multicenter prospective clinical study evaluating long-term safety and efficacy of the polycaprolactone –based dermal filler in nasolabial fold correction. Dermatol Surg 2021, Accepted.
- 20. Converset-Viethel S. A prospective, randomized, controlled, comparative, single-centre study on the safety and effectiveness of Ellansé<sup>®</sup> dermal filler for correction of age-related volume deficit in the mid-face. Internal report 2020.
- Francisco de Melo F, Nicolau P, Piovano L, Lin SL, Baptista-Fernandes T, Martyn I King M, Camporese A, Hong K, Khattar MM, Christen MO. Recommendations for volume augmentation and rejuvenation of the face and hands with the new generation polycaprolactone-based collagen stimulator (Ellansé<sup>®</sup>). Clinical, Cosmetic and Investigational Dermatology 2017:10 431-440.



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