

 ELLANSE®

Treat the signs of
ageing with fast and
long-lasting results

Model is not an actual patient.





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ELLANSÉ. A safe and effective treatment for skin rejuvenation.



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ELLANSÉ does so much more than correct lines and folds. It's a dual-action dermal filler that works deep under the skin to treat the real causes of facial ageing by stimulating the production of the body's natural collagen.

Combining smooth PCL microspheres with a CMC-based carrier gel,¹ 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 youthful infrastructure of the skin.



RESTORE
VOLUME



REDEFINE
CONTOURS



REDUCE
WRINKLES

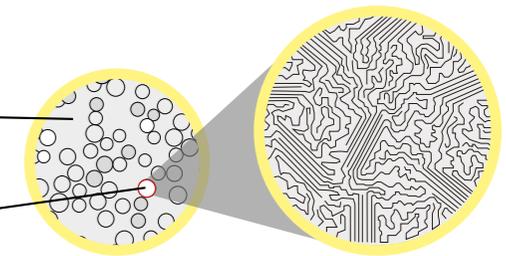


IMPROVE
SKIN QUALITY

A Unique Composition: PCL and CMC¹

70%
Carboxymethyl
Cellulose (CMC)
based carrier gel

30%
Polycaprolactone
(PCL) microspheres



PCL chains within
the microsphere

Innovation for safety and optimal results

Safety

ELLANSÉ achieved the CE Mark (CE 0344) and was launched in 2009.

From its launch, 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.²

In a review of adverse events from launch to December 2020, the adverse event rate was 0.0572% - or 1 event in 1748 syringes.³

ADVERSE EVENT RATE BY TYPE:³

0.0271% Nodules/Lumps	0.0061% Hardness/Induration	0.0009% Infection
0.0206% Swelling	0.0055% Inflammation	0.0016% Bruising/Hematoma

A unique and safe composition.



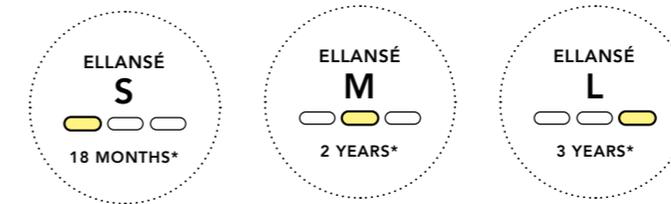
PCL is biodegradable and bioresorbable, naturally hydrolysed by the body into CO₂ and H₂O.⁴



CMC is a widely-used component classified as generally recognised as safe (GRAS).⁴

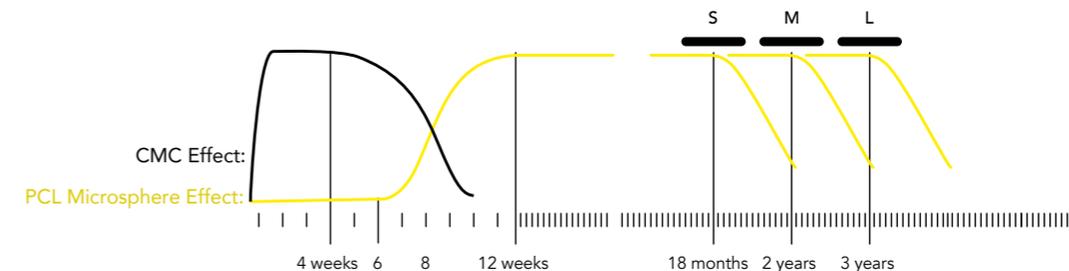
Variable Longevity for Sustained Effectiveness

ELLANSÉ is available in 3 options: S, M and L, with results lasting for 18 months, 2 years and 3 years respectively,* distinguished only by the initial polymer chain length of the PCL.



ELLANSÉ longevity options

The PCL microspheres' unique biodegradation pattern maintains a longer effective lifetime than other dermal fillers, which start to degrade from day one.

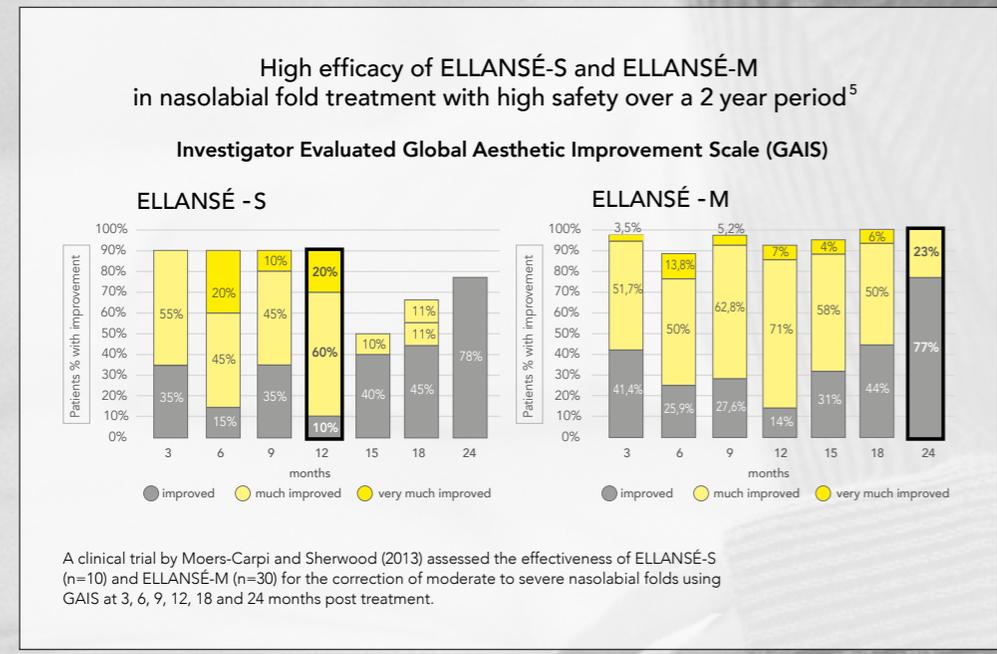


* Expected longevity in-vivo based on extrapolation of clinical data from -S (at least 18 months) and -M (at least 2 years) and accepted PCL degradation behaviour.

Innovation for safety and optimal results

90%
of patients, having undergone an ELLANSÉ S and M treatment, had improved, much improved or very much improved results at 12 months.⁵

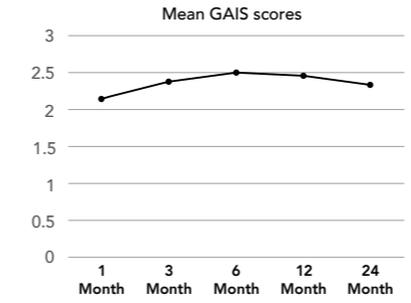
100%
of patients, having undergone an ELLANSÉ M treatment, had improved, much improved or very much improved results at 24 months.⁵



Model is not an actual patient.

ELLANSÉ-M offers immediate and sustained performance⁶

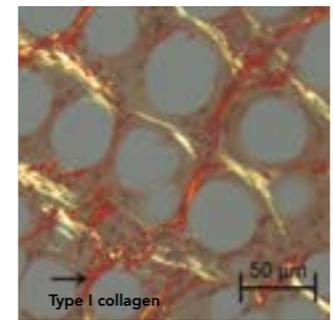
- Efficacy increases notably from 1 to 3 months
- Results are maintained for up to 24 months



Global Aesthetic Improvement Scale (GAIS)
 3 = very much improved
 2 = much improved
 1 = improved
 0 = no change
 -1 = worse

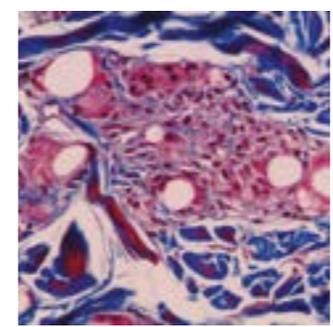
Mean GAIS score over a 24-month period. The scores increased notably from 1 to 3 months, and the scores were well maintained for up to 24 months.

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.⁷



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, a collagen staining).⁸

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.⁹
- Compared to the NASHA-based dermal filler effect, results show that ELLANSÉ achieved the optimal result with a 17% lower injection volume.⁹
- ELLANSÉ was shown to build greater structural support and volumisation, with significantly higher elasticity (G' of 1,000 Pa) than the NASHA dermal filler.⁶
- After neocollagenesis, ELLANSÉ provides an elastic modulus almost equal to that of the dermis and is cosmetically more favourable than an HA dermal filler.⁶

Comparative clinical study of ELLANSÉ versus NASHA for treatment of nasolabial folds⁹



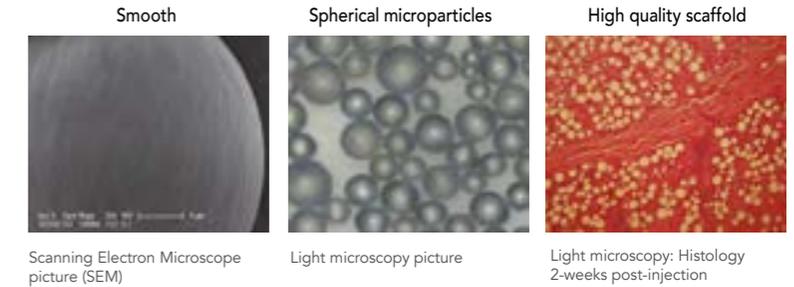
ELLANSÉ versus Collagen Stimulators

Immediate and sustained performance

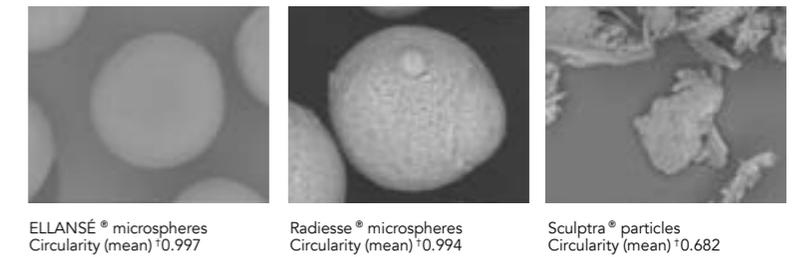
- Collagen stimulation induces long-term volumising capacity, for lasting, natural-looking results from a minimum of 18 months to 3 years.*
- Immediate results compared to Poly-L-Lactic Acid (PLLA)-based filler.
- Improved stability and duration compared to Calcium Hydroxylapatite (CaHA)-based filler.

Smoother, more spherical microspheres.¹⁰⁻¹⁴

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.



COLLAGEN STIMULATOR	POLYMER/MINERAL [†]	SIZE	SHAPE	SURFACE	DURATION
ELLANSÉ®	PCL	25 - 50 µm	Spherical	Smooth	Tunable over 18 - 36 months* ¹⁵
Radiesse®	CaHA [†]	25 - 45 µm	Generally spherical	Smooth	Over 12 months ¹⁶
Sculptra®	PLLA	40 - 63 µm	Irregular	Irregular	25 months ¹⁷



SUMMARY

- 1 Smooth surface compared to PLLA-based filler
- 2 Improved, long-term volume and control of mass loss compared to CaHA-based filler
- 3 Duration of action can be controlled and varied compared to PLLA and CaHA-based fillers

*Expected longevity in-vivo based on extrapolation of clinical data from -S (at least 18 months) and -M (at least 2 years) and accepted PCL degradation behaviour.
 † Roundness calculated by Flow Particle Image Analyser (FPIA).



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.^{18,19} In cases, with results being more significant and longer lasting than other available tested dermal fillers.¹⁹

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.¹⁹

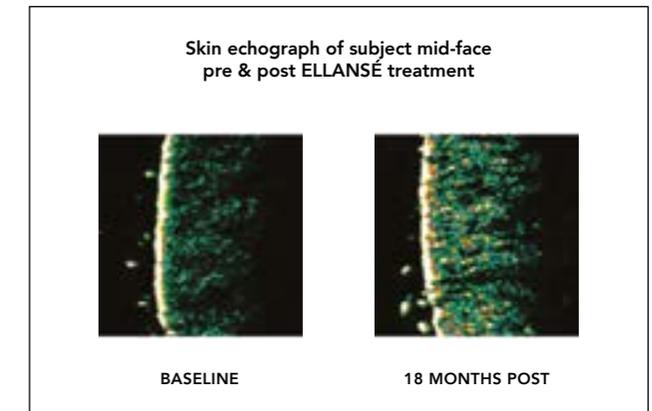
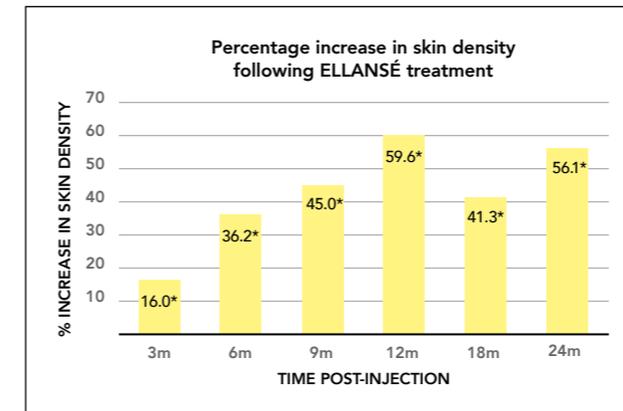
Model is not an actual patient.

ELLANSÉ versus Baseline¹⁹

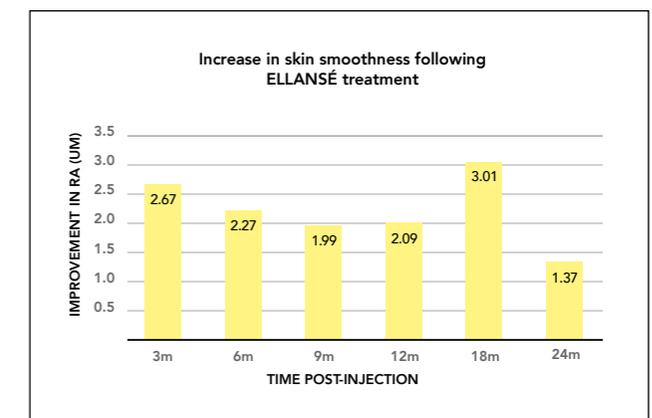
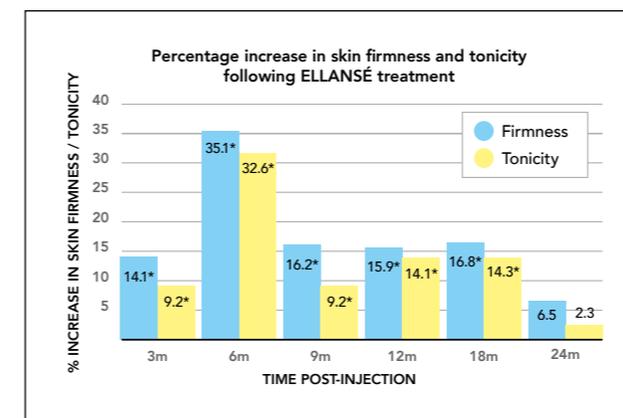
A clinical trial was conducted to assess the effect of ELLANSÉ (n=24) on skin quality parameters at 3, 6, 9, 12, 18 and 24 months post treatment in the mid-face.

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

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



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

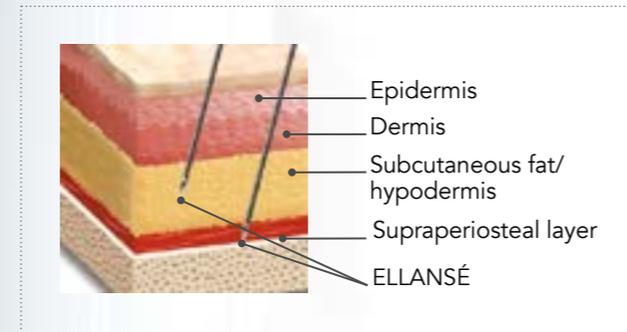




Where to use ELLANSÉ?

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

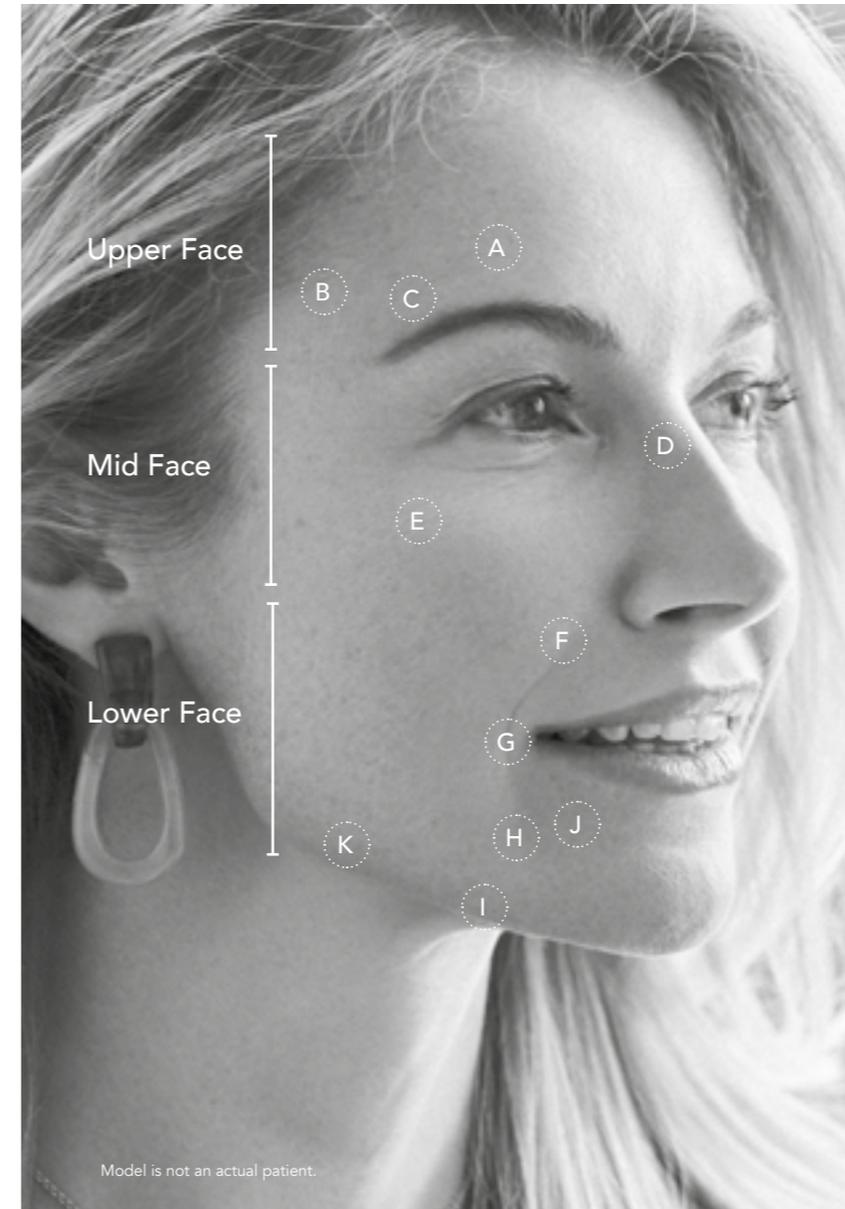
Experts' recommendations provided details on the injection modalities per region (upper, mid and lower face) and per area.²⁰



Did you know?

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

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



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. Prejowl sulcus
- J. Mental crease/
Chin definition
- K. Jawline

Patient Case Studies

PHOTO CREDIT: Dr Sophie Converset. Plastic Surgeon, Lyon, France

Sabine - Age 61

Signs of ageing before ELLANSÉ:

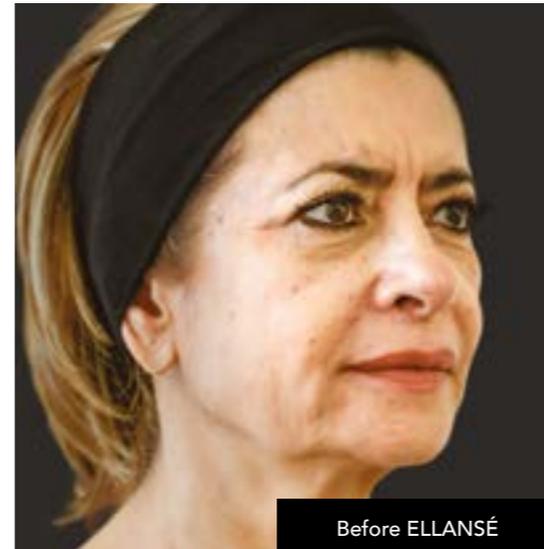
- Sagging face
- Deep facial lines and wrinkles
- Undefined and uncontoured jawline

After ELLANSÉ:

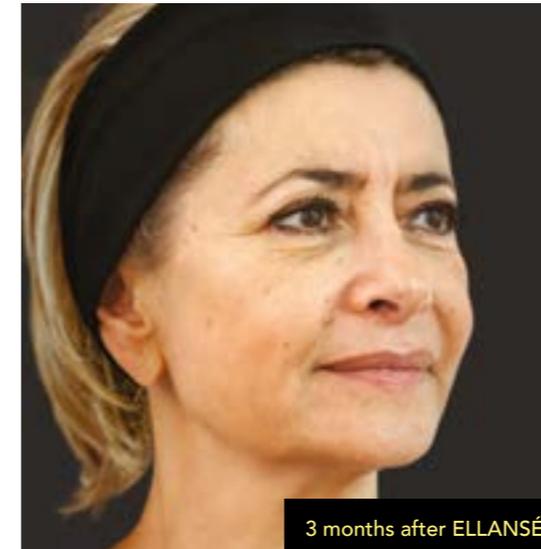
- Softened nasolabial folds
- Jawline definition recreated
- Volume replenished on cheeks and temples

Injection volumes:

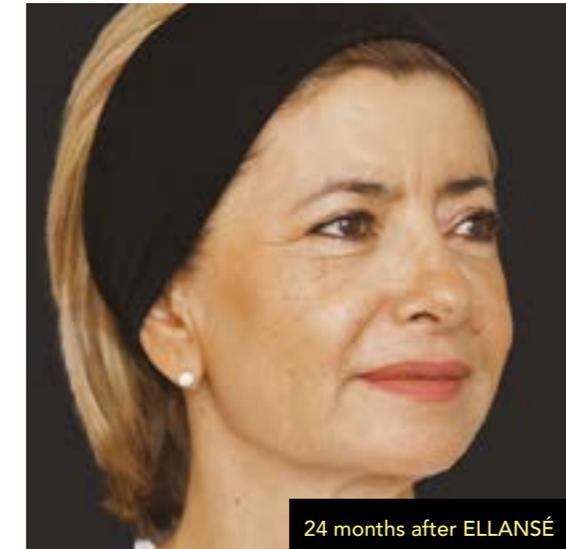
- Temple: 0.5/0.5 ml
- Cheek: 0.7/0.7 ml
- Nasolabial fold: 0.3/0.3 ml
- Jowl: 1/1 ml



Before ELLANSÉ



3 months after ELLANSÉ



24 months after ELLANSÉ

Wu - Age 44

Signs of ageing before ELLANSÉ:

- Loss of upper and mid face volume
- Loss of lower face contouring
- Loss of nose and chin shape

After ELLANSÉ:

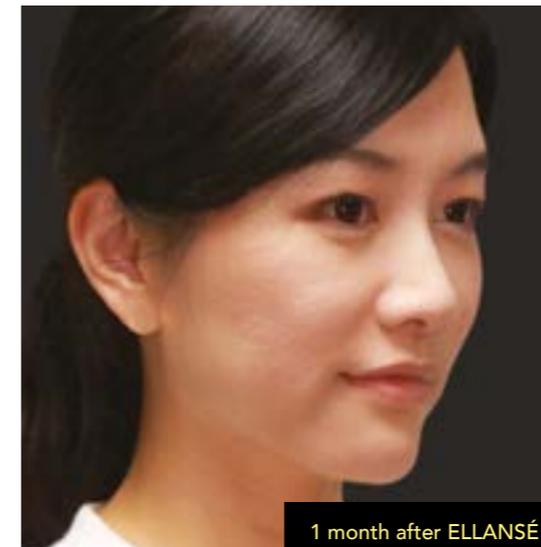
- Increased facial volume
- Rejuvenated facial proportions

Injection volumes:

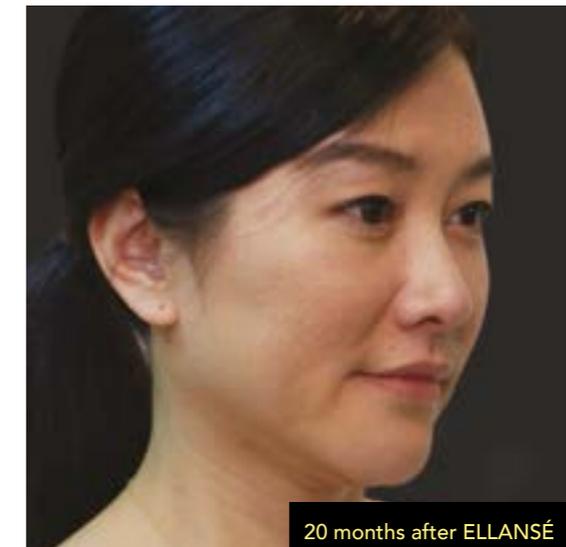
- Eyebrow: 0.8/0.8 ml
- Temple: 0.8/0.8 ml
- Cheek: 1.7/1.7 ml
- Nasolabial fold: 0.8/0.8 ml
- Marionette line: 0.2/0.2 ml
- Jowl: 0.2/0.2 ml
- Chin: 0.7 ml



Before ELLANSÉ



1 month after ELLANSÉ



20 months after ELLANSÉ

PHOTO CREDIT: Dr Shang-Li Lin. Dermatologist, Taipei, Taiwan

Patient Case Studies

PHOTO CREDIT: Dr Sophie Converset. Plastic Surgeon, Lyon, France

Patricia - Age 51

Signs of ageing before ELLANSÉ:

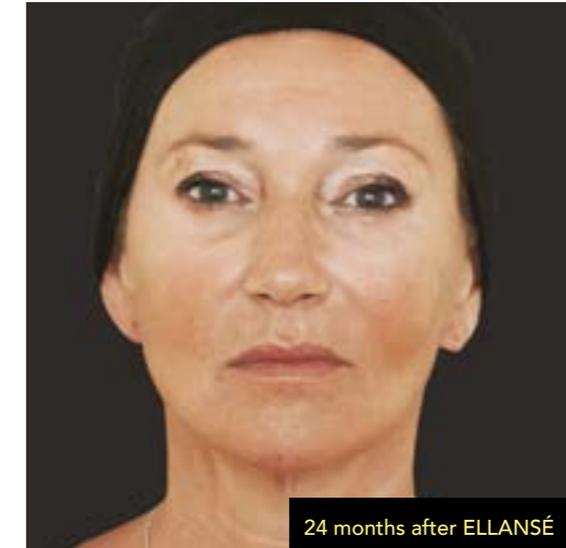
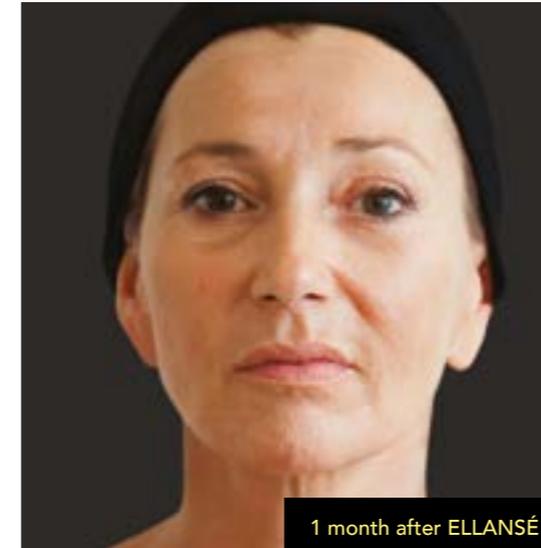
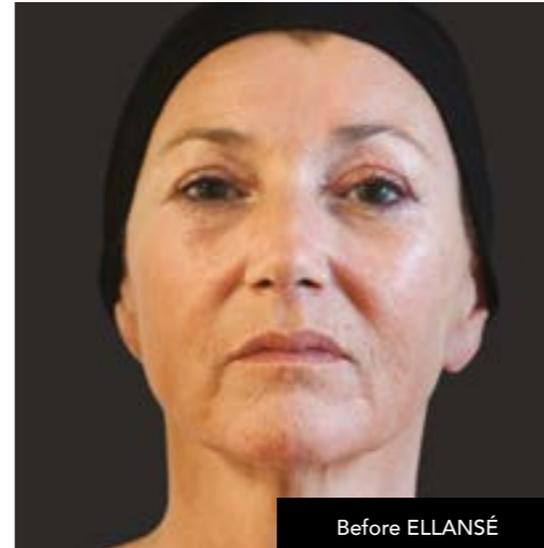
- Deep lines and folds
- Nasolabial folds
- Marionette lines
- Fine lines and wrinkles

After ELLANSÉ:

- Softened nasolabial folds
- Marionette lines diminished
- Improved skin quality

Injection volumes:

- Cheek: 0.5/0.5 ml
- Nasolabial fold: 0.7/0.7 ml
- Marionette line: 0.6/0.6 ml



Anderson Chen - Age 40

Signs of ageing before ELLANSÉ:

- Temporal hollowing
- Eyebrow ptosis
- Infraorbital hollowing
- Lack of zygomatic support
- Sagging cheeks
- Loss of lower face definition

After ELLANSÉ:

- Well-defined masculine facial contour
- Increased facial volume
- Softer nasolabial fold

Injection volumes:

- Eyebrow 0.4/0.4 ml
- Temple 0.2/0.2 ml
- Cheek 1.6/1.6 ml
- Nasolabial folds 0.4/0.4 ml
- Jawline: 0.4/0.4 ml

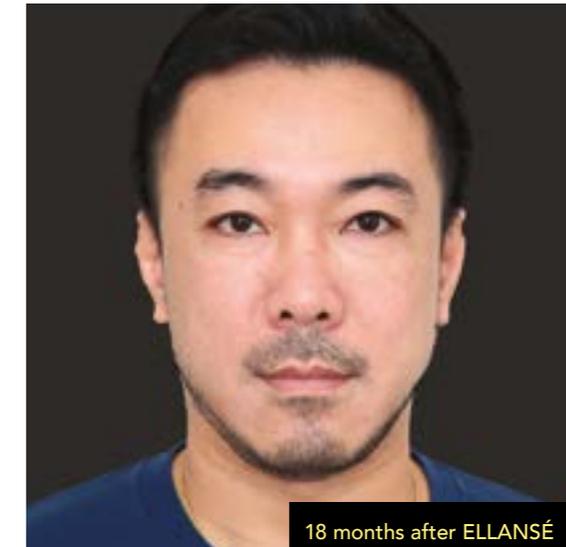
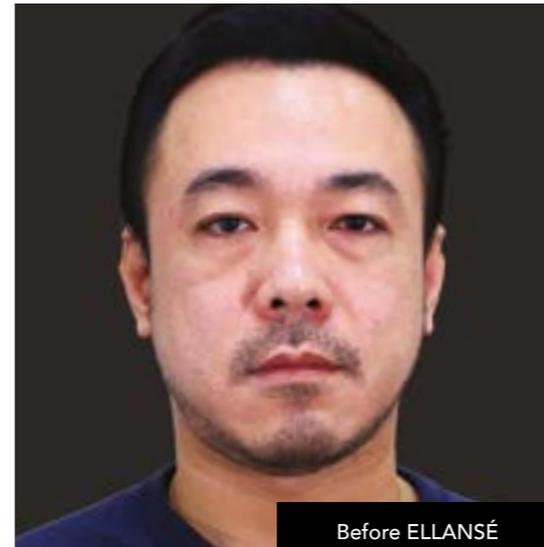


PHOTO CREDIT: Dr Shang-Li Lin. Dermatologist, Taipei, Taiwan

Patient Case Studies

Ginette - Age 59

Signs of ageing before ELLANSÉ:

- Facial lines and wrinkles
- Temporal hollowing

After ELLANSÉ:

- Skin texture improvement
- Facial rejuvenation
- Replenished volume on cheeks and temples

Injection volumes:

Temple: 0.2/0.2 ml

Cheek: 0.2/0.2 ml

Nasolabial fold: 0.5/0.5 ml

Marionette line: 0.6/0.4 ml

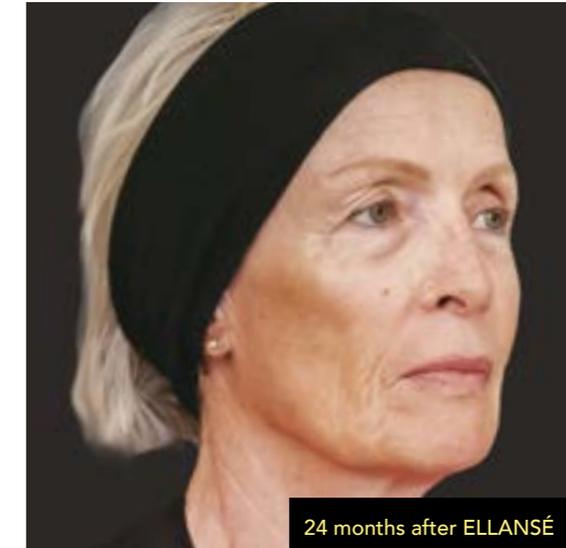
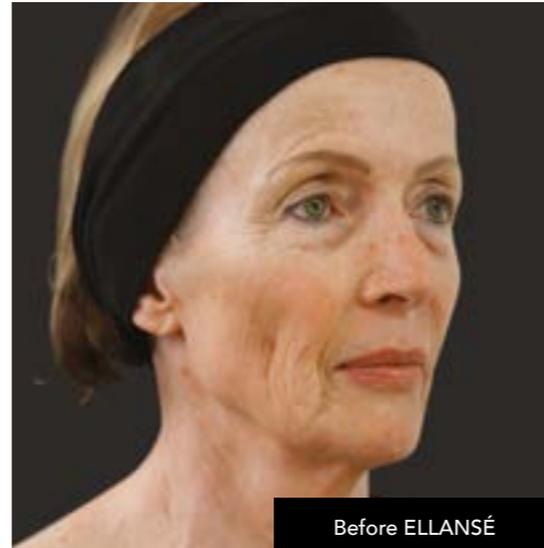


PHOTO CREDIT: Dr Sophie Converset. Plastic Surgeon, Lyon, France

Dominique - Age 67

Signs of ageing before ELLANSÉ:

- Deep lines and folds
- Nasolabial folds
- Marionette lines
- Fine lines and wrinkles

After ELLANSÉ:

- Improved nasolabial folds
- Marionette lines diminished
- Improved skin quality

Injection volumes:

Temple: 0.1/0.1 ml

Cheek: 0.1/0.1 ml

Nasolabial fold: 0.8/0.8 ml

Jowl: 0.6/0.6 ml

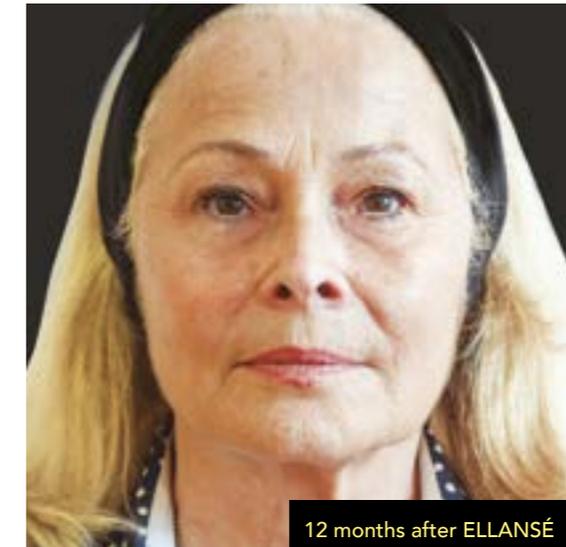
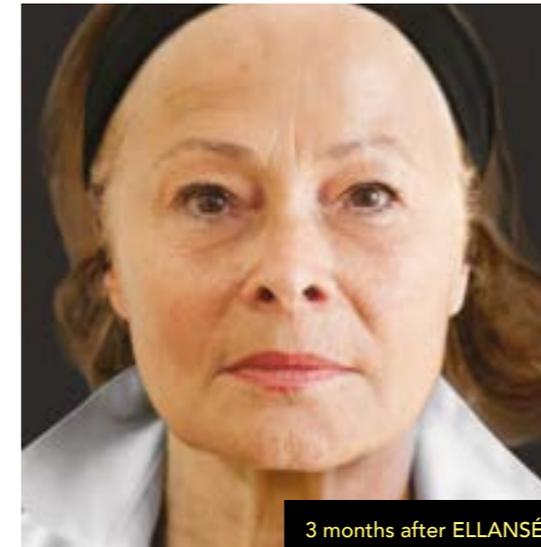
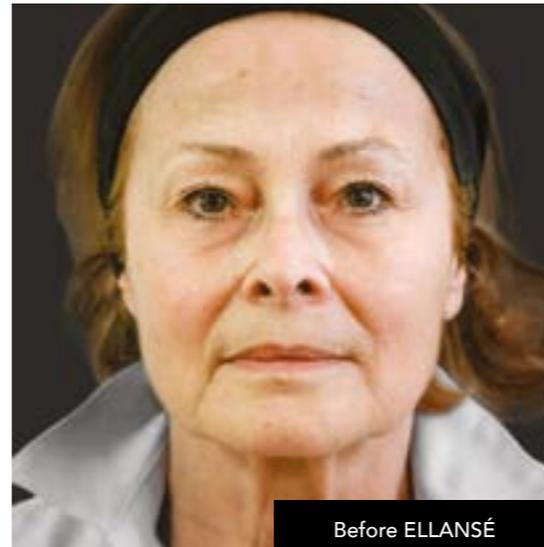


PHOTO CREDIT: Dr Sophie Converset. Plastic Surgeon, Lyon, France



Model is not an actual patient.

High Patient Satisfaction⁵

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

Mean patient satisfaction using Visual Analogue Scale (VAS).



Patient willingness to repeat treatment at 24 months post-injection



Bespoke Bioresorbable Treatment

CE Mark Indication

ELLANSÉ is an injectable implant, indicated for subdermal implantation in the face for the lasting correction of wrinkles and facial ageing signs or conditions.

- Medical Device Class III
- CE mark (CE 0344) obtained in 2009

ELLANSÉ comes in ready-to-use syringes:
2 x 1 ml syringes of ELLANSÉ with 4 x 27G 3/4”
needles depending on variant



ELLANSÉ is available in 3 options
S, M, L, offering a choice of
effectiveness periods.

All other product characteristics are the same
across the entire product range.



ELLANSÉ by Sinclair Pharma.
Support for business and clients.

A complete set of tools to help you in your daily practice

At Sinclair we aim to provide the highest standards
of training and ongoing support. From unparalleled
clinical results and industry-leading safety standards
to marketing tools to help you in your daily practice.

With ELLANSÉ you'll have access to:

- Sinclair College
A premier online educational resource to
support hands-on aesthetic training and provide
additional practice development services.
For further information, please visit:
www.sinclair-college.com
- Specialist ELLANSÉ training
Complete with case study examples and
injection technique videos so you can
create beautiful results every time.
- Help with marketing
Free marketing materials including
promotional waiting room videos,
brochures and aftercare leaflets.



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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®). 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.



Ask your physician for more information.



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