Ellansé®

Summary of Safety and Clinical Performance (SSCP - Switzerland only)

E.MDD.SSCP.01

TABLE OF CONTENTS

LIST OF TABLES

HEALTHCARE PROFESSIONAL SECTION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of Ellansé.

The SSCP is not intended to replace the Instructions for Use (IFU) which is considered to be the main document to ensure safe use of Ellansé, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

1 IDENTIFICATION DEVICE AND MANUFACTURER

1.1 Trade Name

Ellansé®

1.2 Legal Manufacturer

AQTIS Medical B.V.
Yalelaan 44
3584 Utrecht
The Netherlands

1.3 Basic UDI-DI

Ellansé-S: 506003304271809502121 91JR
Ellansé-M: 506003304271809502121 31J7

1.4 Medical device nomenclature

GMDN 61219, Dermal tissue reconstructive material, synthetic polymer

1.5 Classification

Under Medical Device Directive (MDD) 93/42/EEC (as amended), Annex IX, Medical device Class III, Rule 8, Ellansé is a Medical device Class III.

1.6 CE Marking

Ellansé was originally placed onto the EU market as a CE marked Class III medical device by Aqtis Medical in 2009.

1.7 Swiss Authorised Representative

Sinclair Pharma GmbH, Heidelberg (Deutschland) located at:

Zweigniederlassung Gossau SG
Industriestrasse 149, 9200 Gossau SG

1.8 Notified Body

DEKRA Certification B.V.
6825 MJ Arnhem
The Netherlands

Notified body number: 0344

2 INTENDED USE OF THE DEVICE

2.1 Intended Purpose

Ellansé (a Poly-ε-caprolactone (PCL) based dermal filler) is an injectable implant, indicated for subdermal implantation in the face for the lasting correction of wrinkles and facial aging signs or conditions.

2.2 Indication

As per section 2.1, Intended Purpose.

2.2.1 Target Population

Ellansé is intended to be used in adult patients (over 18) whom are not pregnant or breast-feeding and are deemed appropriate for treatment by the physician.

2.3 Contraindications

Refer to the IFU (available on request)

3 DEVICE DESCRIPTION

3.1 Device Description

Ellansé is a sterile, single use, latex-free, non-pyrogenic, bioresorbable, non-permanent implant, whose principle component is synthetic Poly-c-Caprolactone (PCL) microspheres suspended in a carrier gel of phosphate buffered saline (PBS), glycerin and carboxymethylcellulose (CMC).

Variants
Ellansé-S
Ellansé-M

3.2 Product History

Refer to section 1.7.

3.3 Accessories

Ellansé is supplied with four 27G needles which are purchased as CE marked devices.

3.4 Combinations

Ellansé is not required to be used in combination with any other device to meet its intended purpose. It is considered a stand-alone device.

4 RISKS and WARNINGS

4.1 Residual Risks and Undesirable Effects

These warning instructions have been applied following a comprehensive risk assessment which has been carried out in accordance with the latest and relevant international standard, ISO 14971 and no residual risks remain. Consideration to the intended user of these products, i.e. healthcare professional, has been made when wording the warnings.

The Ellansé devices have been deemed suitable for use in adults based on the safety profile of the products and their equivalents and the small numbers of adverse events (AE) associated with use. Any undesirable side-effect constitutes an acceptable risk when weighed against the performances intended.

4.1.1 Side Effects/ Adverse Events

Refer to the IFU (available on request).

4.2 Warnings and Precautions

4.2.1 Warnings

Refer to the IFU (available on request).

4.2.2 Precautions for Use

Refer to the IFU (available on request).

4.3 Field Safety Corrective Action (FSCA), Field Safety Notice (FSN)

Ellansé has not been the subject of any FSCA’s or FSN’s to date.

5 SUMMARY OF CLINICAL EVALUATION

5.1 Summary of Clinical Data from Equivalent Devices

The data presented within the Clinical Evaluation Report (CER) is based on an analysis of available clinical literature and post market clinical data relevant to the intended use and the clinical experience of Ellansé and/ or products with similar design characteristics.

Clinical studies on the identified devices demonstrated clinical efficacy, and the long-term safety and performance of the devices are confirmed.

5.2 Summary of clinical data of the Device

Studies assessing the safety and performance of Ellansé provide pivotal data supporting the device range. Summary information from all studies on Ellansé is shown in Table 1.

Table 1 Ellansé Clinical Studies

Study	Products	Duration of Effect
Hongyi (2019)	Ellansé-S (n=80) Restylane 2 (n=80)	Moderate to severe nasolabial folds (12 months)
Kim (2019)	Ellansé-M (n=117)	Forehead, anterior cheek, and left side of the temple (1-4 years)
Converset-Viethel (2018)	Ellansé-S (n=12) Ellansé-M (n=12)	Mid-face (12 months)
Kestemont (2018)	Ellansé-S (n=90)	Nasolabial Folds (12-18 months)
Bae et al. (2016)	Ellansé-M (n=58)	Forehead Augmentation (24 months)
Galadari et al. (2015)	Ellansé-S Perlane (n=40)	Nasolabial Folds (12 months)
Moers-Carpi and Sherwood (2013) (n=40)	Ellansé-S Ellansé-M	Nasolabial Folds (S = 12 months M = 24 months)
Gritzalas (2011) (n=40)	Ellansé-S Ellansé-M	Facial volume loss (12-15 months)
Goodwin (2018)	Ellansé-S (n=2)	Facial volume loss (12 months)
Lin (2018)	Ellansé-S (n=1)	Facial volume loss (12 weeks)

5.3 Overall summary of clinical performance

MDD requires an evaluation of safety and efficacy of the devices to be certified. The CER is performed based on MDD 93/42/EEC part A as well as MEDDEV-Guideline 2.7/1. “Evaluation of Clinical Data”.

The Ellansé products correct for volume loss. The therapeutic benefit of the Ellansé range is to correct age-related volume loss due to increased skin laxity, fat loss / fat redistribution and diminished support from underlying muscle and bone which results in wrinkles and facial aging signs.

Ellansé has an acceptable benefit/risk profile according to current knowledge/ the state of the art in the medical fields concerned and according to available medical alternatives. Studies on Ellansé have demonstrated safety and effectiveness in a variety of indications with up to 2 years duration of effect for individual variants.

5.4 Post Market Clinical Follow Up (PMCF)

The adverse event rate for Ellansé is considered to be low and acceptable. The safety profile of Ellansé is well established. Further post market studies are in discussion.

6 THERAPEUTIC ALTERNATIVES

Ellansé dermal fillers offer a minimally invasive technique that is a non-permanent alternative to more permanent fillers, laser treatments, or more involved surgical procedures, such as permanent plastic surgery.

Other dermal fillers, such as collagen, calcium hydroxylapatite, HA and poly-L-lactic acid (PLLA) microspheres are commonly used for facial rejuvenation. Most dermal fillers are passive space filling agents (i.e., volumisers); however, other more deeply implanted agents, such as calcium hydroxylapatite and poly-L-lactic acid, can be classified as stimulators. All of these products can be used in facial augmentation, whether used solely or combined. Volumisers increase volume and fill out skin directly. Stimulators can also directly create volume but also stimulate a long-term or permanent collagen deposition. Some fillers such as Ellansé, exhibit both actions and fall into both categories.

6.1 Age related volume loss

Ellansé is an injectable implant, indicated for subdermal implantation in the face for the lasting correction of wrinkles and facial aging signs or conditions. RCTs (Randomised controlled trial?) by Galadari et al. (2015) and Moers-Carpi and Sherwood (2013) showed that sustained performance was demonstrated for Ellansé-S up to 12 months and Ellansé-M up to 24 months.

6.2 Atrophic scars and HIV facial lipoatrophy

Pivotal data from equivalent devices indicates how safe and effective dermal fillers containing polyester micro particles perform in treating conditions, such as HIV-associated facial lipoatrophy and atrophic scars. The main ingredient in Ellansé (PCL) demonstrates equivalence with similar polyester dermal fillers containing PLLA. They are based on the same polymer platforms with the same chemical structures and share the same method of resorption. Whilst all the products behave in a similar manner, Ellansé can offer additional benefits in terms of handling and ease of use for the physician, increase in reproducibility, reduction in discomfort for the patient, and increase in safety for the patient.

Effective treatment with Sculptra was demonstrated by Sapra et al. (2015) in the temples and cheeks for atrophic scars.

Bohnert et al. (2020) assessed the improvement in skin quality of Sculptra Aesthetic compared with saline (bacteriostatic water) injections in the submalar/mid cheek area. This study demonstrated that repeated Sculptra injections improved skin quality and were consistent with the results from the unpublished study assessing the equivalent Ellansé (Converset-Viethel 2018).

7 SUGGESTED PROFILE AND TRAINING FOR USERS

Ellansé should only be used by trained practitioners in the field of soft tissue augmentation.

The IFU states that 'Only be used by health care providers with expertise in the correction of volume defects after fully familiarizing themselves with the product and its complete instruction leaflet'. ‘This device should only be used by trained practitioners in the field of soft tissue augmentation’

Additional training materials are available on request from Sinclair Pharmaceuticals Ltd.

8 APPLIED STANDARDS

Table 2 details the applied standards for the device.

Table 2 Applied Standards

Directives/ Regulation
Directive 93/42/EEC
Standards
EN 556-1
EN 556-2
EN ISO 10993-3
EN ISO 10993-5
EN ISO 10993-7
EN ISO 10993-9
EN ISO 10993-11
EN ISO 10993-12
EN ISO 10993-13
EN ISO 10993-17
EN ISO 10993-18
EN ISO 11137-1
EN ISO 11137-2
EN ISO 11737-2
EN ISO 13408-1
EN-ISO 13485
EN ISO 14155
EN ISO 14971
EN ISO 14937
ISO 15223-1
EN-ISO 17665-1
EN 868-5
EN 1041
EN ISO 1628-1
EN ISO 7886-1
EN ISO 10993-1
EN ISO 10993-6
EN ISO 10993-10
EN ISO 10993-16
EN ISO 11135
EN ISO 11137-3
EN ISO 11138-2
EN ISO 11138-3
EN ISO 11607-1
EN ISO 11607-2
EN ISO 11737-1
EN ISO 14630
EN ISO 14644-1
EN ISO/IEC 17050-1
EN IEC 62366-1
EN ISO 7864
Guidelines
MEDDEV 2.1/1
MEDDEV 2.4/1
MEDDEV 2.7/1
MEDDEV 2.12/2
MEDDEV 2.12/1
ICH guidelines Q1A
GHTF SG5/N2R8
European Pharmacopoeia

Ph.Eur 2.6.1
Ph.Eur 2.6.12

9 CONCLUSION

Ellansé has an acceptable benefit/risk profile according to current knowledge/the state of the art in the medical fields concerned and according to available medical alternatives. Studies on Ellansé and equivalent devices have demonstrated safety and effectiveness.

The information supplied with the device are reflective of the safe and effective use of the device in its intended applications, and the intended purpose and risk reduction measures are adequate.

10 REFERENCES

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Bohnert K, Dorizas A, Lorenc P, Sadick NS. (2019) 'Randomized, Controlled, Multicentered, Double-Blind Investigation of Injectable Poly-L-Lactic Acid for Improving Skin Quality'. *Dermatol Surg.* 45(5), pp: 718-724.

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Kestemont (2018) 'Safety and efficacy study of ELLANSE-S, a polycaprolactone collagen stimulator. Interim report after the follow-up visit at 18 months'. *Unpublished. 28th November 2018*.

Kim JS. (2019) 'Changes in Dermal Thickness in Biopsy Study of Histologic Findings After a Single Injection of Polycaprolactone-Based Filler into the Dermis'. *Aesthet Surg J.* 39(12):NP484-NP494

Lin SL. (2018) 'Polycaprolactone facial volume restoration of a 46-year-old Asian women: a case report'. *J Cosmet Dermatol.;* 17, pp: 328–332.

Moers-Carpi MM, Sherwood S (2013) 'Polycaprolactone for the correction of nasolabial folds: a 24-Month, prospective, randomized, controlled clinical trial'. *Dermatol Surg* 39, pp: 457–463

Sapra S, Stewart JA, Mraud K, Schupp R (2015) 'A Canadian study of the use of poly-L-lactic acid dermal implant for the treatment of hill and valley acne scarring'. *Dermatol Surg.* 41(5), pp: 587-94.