Lanluma®

Summary of Safety and Clinical Performance

(SSCP – Switzerland only)

LL.MDD.SSCP.01

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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 Lanluma®.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, 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

LANLUMA®

**The product is currently registered as GANA by GANA R&D Co., Ltd. however Sinclair market the product under the trade name LANLUMA®*

1.2 Legal Manufacturer

The Legal Manufacturer, is:

GANA R&D Co., Ltd. located at:

905, 555, Dunchon-daero,
Jungwon-gu, Seongnam-si
Gyeonggi-do, Korea

The distributor for Lanluma is Sinclair Pharmaceuticals Ltd.

1.3 Medical device nomenclature

GMDN 61219, Dermal tissue reconstructive material, synthetic polymer

1.4 Classification

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

1.5 CE Marking

Under Annex IX of MDD this poly-L-lactic acid (PLLA) based medical device has been CE marked since 2019.

1.6 EU Authorised Representative

Clinic Medical AB located at:

Hamringev, 1, 146, 41
Tullinge, Sweden

1.7 Swiss Authorised Representative

Sinclair Pharma GmbH located at:

Heidelberg (Deutschland), Zweigniederlassung Gossau SG
Industriestrasse 149, 9200 Gossau SG

1.8 Notified Body

ITC INSTITUT PRO TESTOVANI A CERTIFIKACI, a.s.
Tomáše Bati 299,
763 02 Zlín, Czechia

Notified body number: 1023

2 INTENDED USE OF THE DEVICE

2.1 Intended Purpose

Lanluma is a poly-L-lactic acid (PLLA) injectable implant, intended for increasing the volume of depressed areas, particularly to correct skin depressions.

2.2 Indication

As per section 2.1, Intended Purpose.

2.2.1 Target Population

Lanluma is intended to be used in adult patients (over 18) whom are not pregnant or breast feeding.

2.3 Contraindications

Refer to the IFU (available on request).

3 DEVICE DESCRIPTION

3.1 Device Description

Lanluma is a PLLA implant in the form of a sterile non-pyrogenic suspension, which is reconstituted from a sterile dry powder by the addition of sterile water for injection. This suspension contains microparticles of poly-L-lactic acid, the crystalline from of polylactic acid. Poly-L-lactic acid is a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. Lanluma's principal ingredient, PLLA, provides results that appear gradually and last more than two years (Rhoda SN et al., 2010) also dependant on the medical practitioner injection technique, injection location, injection depth, motion, lifestyle, age, and gender.

The only difference between the Lanluma models X & V is the quantity of the product.

3.2 Product History

Refer to section 1.5.

3.3 Accessories

There are no accessories supplied with Lanluma.

3.4 Combinations

Lanluma is provided as a sterile product, in a clear glass vial and includes two (2) models, each with different capacity.

Lanluma is not for use in combination with any other device. It is considered a stand-alone device.

4 RISKS and WARNINGS

4.1 Residual Risks and Undesirable Effects

The warning instructions supplied with the product have been applied with consideration of the user and following a comprehensive risk assessment carried out in accordance with the latest and relevant international standard, ISO 14971 and no residual risks remain.

Lanluma 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)

Lanluma 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 Lanluma 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 Lanluma provide pivotal data supporting the device range. Summary information from the clinical study on Lanluma is shown in Table 1.

Table 1 Lanluma Clinical Study

Study (n)	Products	Duration of Effect
Seo Yoon Pyo et al. (2018) (n= 70)	Lanluma V® Sculptra®	Non-inferiority and safety of Lanluma V compared to Sculptra after 96 weeks for the increase in volume of depressed areas, particularly to correct skin depressions.

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 Annex X MEDDEV-Guideline 2.7/1. “Evaluation of Clinical Data”.

The Lanluma products are suitable for increasing the volume of depressed areas, particularly to correct skin depressions. The use of PLLA dermal filler injections into different levels of the skin to improve a patient's physical features by augmenting superficial soft tissue for correction of depressions.

Lanluma 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. The clinical study on Lanluma in combination with the clinical studies of the equivalent device have demonstrated safety and effectiveness.

5.4 Post Market Clinical Follow Up

The adverse event rate for Lanluma is considered to be low and acceptable. The safety profile of PLLA used within Lanluma is well established. Further post market studies are planned.

6 THERAPEUTIC ALTERNATIVES

6.1 Age related volume loss

Using dermal fillers is a minimally invasive technique that offers a non-permanent alternative to more permanent fillers, laser treatments, or more involved surgical procedures, such as permanent plastic surgery. Dermal fillers, such as collagen (bovine, human, and purified porcine), calcium hydroxylapatite, and injectable medical devices such as PLLA, are commonly used for facial rejuvenation. Most dermal fillers are passive space filling agents; however, other more deeply implanted agents, such as calcium hydroxyapatite and PLLA, are products that are capable of increasing fibroblast activity, which is thought to stimulate nucleogenesis. All of these products can be used in facial augmentation, whether used solely or combined (Sherman, 2009).

Since the introduction of the first dermal fillers to the USA in 1981, the practice of minimally invasive facial rejuvenation has grown exponentially. In 2010, US physicians performed more than 1 million injectable HA treatments alone (Breithaupt et al. 2012).

Fillers can also be classified according to their mechanism of action: volumisers i.e., Volume fillers and stimulators i.e., tissue stimulating agents. 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 exhibit both actions and fall into both categories.

7 SUGGESTED PROFILE AND TRAINING FOR USERS

Lanluma should only be used by health care professionals trained in the field of soft tissue augmentation. These medically trained professionals must be approved by local regulations and be familiar with anatomy (e.g., medical professionals such as physicians/doctors, aesthetic physicians, nurses, dentists).

The IFU states ‘This product should only be used by a physician who is fully familiar with the product, product educational materials, and the entire package insert and patient labelling’.

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

8 APPLIED STANDARDS

Table 2 details the applied standards referenced for the device. Other standards and later versions of standards may also apply.

Table 2 Applied Standards

Standard Identification
EN1041
EN ISO 15223-1
EN ISO10993-1
EN ISO10993-3
EN ISO10993-5
EN ISO10993-6
EN ISO10993-10
EN ISO10993-11
EN ISO 10993-12
EN ISO11137-1
EN ISO11137-2
EN ISO11737-1
EN ISO11737-2
EN ISO13485
EN ISO 14630
EN ISO 14644-1
EN ISO 14644-2
EN ISO14971
EN ISO14155
ASTM F1980 -16
USP 36
European Pharmacopoeia
MEDDEV 2.12_2 Rev.2
MEDDEV 2.12-1Rev.8
MEDDEV 2.7/1 Rev.4

9 CONCLUSION

Lanluma 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. The clinical study on Lanluma and studies on equivalent devices have demonstrated effectiveness. Reported effectiveness in literature for PLLA is up to 2 years (Rhoda SN et al., 2010).

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

Further post market studies are planned.

10 REFERENCES

Breithaupt AD, Custis T, Beddingfield F. (2012) 'Next-Generation Dermal Fillers and Volumizers. *Cosmet Dermatol'* vol. 25, pp. 184-191.

Rhoda SN, Leslie B, Fredric SB, Steven F, Scott G, Nicholas JL, Gary DM, Marta I R, Rod JR, Wm PW (2010), 'A randomized study of the efficacy and safety of injectable poly-L-lactic acid versus human-based collagen implant in the treatment of nasolabial fold wrinkles' vol. 62, no. 3, pp. 448-62.

Seo YP, Cho JH, R Bong Il (2018), 'Clinical Trial Report for Effectiveness and Safety Evaluation of Clinical Application of GANA V versus Sculptra® in patients after correction for skin depressions', retrieved from GANA R&D Co., Ltd clinical study.

Sherman RN. (2009) 'Avoiding dermal filler complications'. *Clinics in Dermatology* 27: S23–S32.