LANLUMA®

What is behind its enviable safety profile?

BEST
INJECTABLE
BODY FILLER
AMWC AWARDS
2023

Model is not an actual patient.

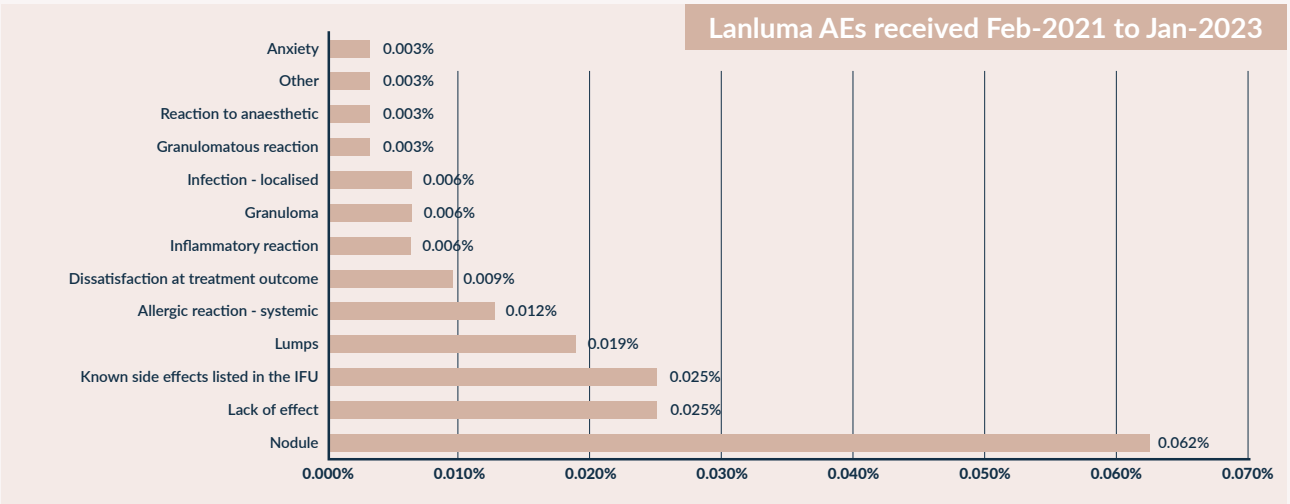
What is Lanluma?

- Lanluma is an injectable poly-L-lactic acid (PLLA) collagen stimulator for face and body. CE marked (CE 1023) Lanluma is intended for increasing the volume of depressed skin areas, particularly to correct skin depressions. It is designed to treat many body areas such as the abdomen, buttocks, thighs, upper-arms, hands, décolleté, neck, face and associated cellulite.
- Lanluma comes in 2 convenient presentations with the exact same composition but different vial size to cover different needs:

Lanluma V contains 210 mg PLLA designed for small areas.
Lanluma X contains 630 mg PLLA for bigger body areas.

Lanluma, an enviable safety profile

- The correct reconstitution, dilution, and administration of Lanluma contribute to its effectiveness and safety. Therefore, administering the product using optimal techniques can improve treatment outcomes while also reducing the occurrence of adverse events (AEs).[1-4] *
- **Lanluma has an enviable safety profile**
  - Evidence based on the post-market surveillance compiling the adverse events (AEs) reported worldwide since the February 2021 launch until end of January 2023
  - AEs overall incidence of 0.19% (1 event every 526 vials)
  - No vascular complications reported since the launch
  - No unexpected AEs reported
  - No product defects found responsible for AEs occurrence



However as for any fillers, adverse events may occur, that are mostly mild and often resolve spontaneously. Some of the reasons for the occurrence of AEs (injection-technique related) include:
- Overcorrection[5]
- Improper, superficial placement[5,6]
- Too much product in one area can lead to nodules[7]

The types of AE reported with Lanluma are presented above, the most frequent being nodules.[3,4]
Sinclair in collaboration with a board of leading physicians in the field of aesthetics, has developed a series of steps to be taken for preventing AEs. Physicians should report any adverse event promptly by sending the information to quality@sinclair.com. For complete information, please refer to the Lanluma V and Lanluma X IFUs available at https://eifu.sinclairpharma.com.

*AEs are defined as an unexpected medical problem that happens during treatment with a drug or other therapy. AEs events may be mild, moderate, or severe, and may be caused by something other than the drug or therapy being given.[5-8]

Lanluma, stability after reconstitution

A reconstitution study*:

- Showcasing the safety and efficacy of Lanluma is essential to ensuring that physicians can confidently prescribe it to their patients. Sinclair has generated additional data on the behaviour of Lanluma since this is key in addressing general concerns about clogging and correct hydration with PPLA.
- By conducting a comparative analysis of Lanluma *vs* the PLLA reference product on the market, we can evaluate the performance of Lanluma and provide physicians with more comprehensive information to guide their prescribing decisions.

*Data on file

Lanluma behaviour at different times after reconstitution and mixing: a comparative study

Both products were manually mixed for 1 minute before resting at room temperature.

Scan to watch the full study

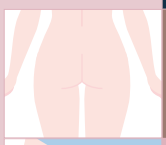
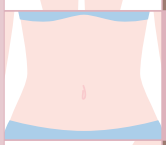
Key findings:

- After reconstitution, Lanluma stays stable for a longer period of time at the same concentration than a competitor's product whose PLLA particles appear to separate and settle at the bottom and at the top more quickly. A similar behaviour can occur in the syringe during the application.
- The rapidity of the reconstitution and the homogenous product obtained could contribute to avoiding clogging.

Lanluma, recommendations for use

- For optimal safety, it is important to respect specific recommendations depending on area treated for volume, dilution and type of cannula used.
- Lanluma is Intended to be administrated via injection by a trained and authorized health professional. Opinions and methods presented here are based on the experience of physicians. Refer to instructions for details of specific indications.
- A set of protocols was developed in collaboration with a board of leading physicians in the field of aesthetics for each of the indications of Lanluma. Harmonized protocols allow new Lanluma users to be trained and provide a consistent guide to all Lanluma to be used safely in all countries. For a safe injection, Lanluma should be injected subdermaly and according to each treatment protocol.

The recommendations of accessories and safe volumes for injection [table below] have been extracted from the Lanluma treatment protocols:

	Area	Volume	Dilution	Device	Full protocol
	**Buttocks**	1 to 2 vials of **Lanluma X** per side*	Simple dilution [40 ml]	**18G** cannula	
	**Cellulite**	Up to 1 vial of **Lanluma V** for both sides	Double dilution [30 ml]	**18G – 23G** cannula	
	**Thighs**	1 to 2 vials of **Lanluma V** per leg per session*	Double dilution [30 ml]	**21G** cannula	
	**Abdomen**	1 to 2 vials of **Lanluma V****	Double dilution [30 ml]	**21G – 23G** cannula	
	**Upper arm**	Up to 1 vial of **Lanluma V** per arm	Double dilution [30 ml]	**21G – 23G** cannula	
	**Face**	1 vial of **Lanluma V**	Simple dilution [15 ml]	**21G – 23G** cannula	
	**Neck**	2 ml of **Lanluma V** per side.	Double dilution [30 ml]	**22G – 23G** cannula	
	**Décolleté**	10 ml up to 15 ml of **Lanluma V** per side	Double dilution [30 ml]	**23G** cannula	
	**Hands**	Up to 1 ml of **Lanluma V** per hand	Double dilution [30 ml]	**21G - 22G** cannula	

*The choice to use 2 vials of Lanluma following the first session is at the clinician's discretion and should be based on the patient's response to the product during the first session and the intended outcome of treatment. **Depending on abdominal size, using 5 ml per 10 cm-by-10 cm area.

Lanluma, key features

- Lanluma is made of PLLA, a biocompatible, biodegradable and bioresorbable polymer that has been safely used in many applications and in medicine for more than 30 years. [9]
- Lanluma has been shown to offer good clinical safety and efficacy through evidence obtained from the daily practice of physicians and clinical data. Lanluma has proven equivalent efficacy as established in the WSRS* and the GAIS** scores after 48 weeks compared to PLLA reference product. [8]
- Treatment protocols dedicated to the most frequently treated areas allow optimal outcomes in safe conditions. They are an important tool for physician training and practice worldwide, providing a consistent guide for the safe use of Lanluma.
- PLLA, the main ingredient in Lanluma, provides results that last more than 2 years. [10]
- Lanluma can be easily and quickly reconstituted. It can be injected at the first consultation.
- It is a versatile product; it can be used in face and body indications.

> *Lanluma is a fundamental in my treatments since it is a product that is very versatile and effective. Its results are very natural, and it not only corrects the signs of flaccidity in the face and body but works by regenerating our own collagen preventing the signs of ageing on the skin of both the face and body.*
>
> ***Dr Beatriz Beltran***,
> *Dermatologist, Spain*

> *What I like the most about Lanluma treatments is the safety profile. After four years of doing treatments, I have never had any adverse reactions, allergies, nodules, or late onset granulomas. Of course, a good learning program is needed for the injector, but then patients and doctors fall in love forever with the best collagen inductor available on the market!*
>
> ***Dr Francesca De Angelis***,
> *Plastic Surgery Specialist, Naples (Italy)*

1. Narins RS. Minimizing adverse events associated with poly-L-lactic acid injection. Dermatol Surg. 2008 Jun;34 Suppl 1:S100-4.

2. Vleggaar D. et al. The need for consensus recommandations on the use of injectable poly-L-lactic acid for facial and nonfacial volumization. J Drugs Dermatol. 2014 Apr;13(4 Suppl):s28.

3. Vleggaar D, Fitzgerald R, Lorenc ZP, Andrews JT, Butterwick K, Comstock J, Hanke CW, O'Daniel TG, Palm MD, Roberts WE, Sadick N, Teller CF. Consensus recommandations on the use of injectable poly-L-lactic acid for facial and nonfacial volumization. J Drugs Dermatol. 2014 Apr;13(4 Suppl):s44-51.

4. Redaelli A, Rzany B, Eve L, Grangier Y, Herranz P, Olivier-Masveyraud F, Vleggaar D. European expert recommendations on the use of injectable poly-L-lactic acid for facial rejuvenation. J Drugs Dermatol. 2014 Sep;13(9):1057-66.

5. Russell E, et al. Complication of dermal filler. J Ent Masterclass 2019;12:50-54.

6. Chiang YZ, et al. Dermal fillers: pathophysiology, prevention and treatment of complications. J Eur Acad Dermatol Venereol 2017;31:405-13.

7. Christen MO, Vercesi F. Polycaprolactone: how a well-known and futuristic polymer has become an innovative collagen-stimulator in esthetics. Clin Cosmet Investig Dermatol. 2020 Jan 20;13:31-48.

8. Clinical Trial Report GN-CIR-01, version 1.0_20190104.

9. Christen MO. Collagen stimulators in body applications: A review focused on Poly-L-Lactic Acid (PLLA). Clin Cosmet Investig Dermatol. 2022 Jun 21;15:997-1019.

10. Narins RS, et al. 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. J Am Acad Dermatol. 2010;62:448–62.

* WSRS, Wrinkle Severity Rating Scale.

** GAIS, Global Aesthetic Improvement Scale.

LANLUMA®

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