# Information and Consent for Lanluma

**Important Background to the Consent Process**

Your clinician wishes to help you make an informed decision about your treatment options and any relevant alternative options. You may at any time decline treatment even after giving your consent.

Whilst your clinician will make every effort to understand what significance you would attach to any particular risk it is important to us that you feel comfortable enough to question the clinician on any point of concern during this process. Please feel you have as much time as you wish to reflect on the information given before agreeing to proceed with the treatment.

**Purpose of Treatment**

You have presented with concerns which have formed the basis of a clinical discussion and examination. The purpose of the proposed treatment is to address your concerns either individually or in combination with other modalities of treatment.

**Outcomes**

Your clinician will endeavour in good faith to employ the principles of best practice in delivering your treatment. Each patient is individual and response to treatment will vary from patient to patient and treatment to treatment. As such it is difficult to guarantee outcomes will always meet your expectations.

**Background Information**

Lanluma is designed to restore facial volume and to provide tissue enhancement to the face. It has also been shown to improve the quality of the skin, giving a natural healthy glow. Treatment is given under topical, or local anaesthetic in the minor procedure room. Results are gradual, and achieved over a number of treatments, determined by the degree of correction. The substance injected causes a reaction within the skin or tissues to activate the production of new and healthy skin cells.

**Commonly Experienced Adverse Events**

Swelling
Tenderness
Redness
Pain at injection site
Bruising
Bleeding
Itching
Infection

**Less Common Risks**

Nodules or other palpable asymptomatic skin changes at the injection site
On extremely rare occasions, a risk of vascular occlusion causing necrosis or blindness has been reported

**Important Considerations**

Every care is taken to deliver the products in a manner which will minimise risk, however you should be aware of the risks, as one may exist upon which you place particular significance.
Patients are advised to take in to account all these potential risks before consenting to treatment. Please make your clinician fully aware of your expectations prior to giving consent.

**Safety Profile**

When performed by a trained professional, treatment with Lanluma is generally considered a safe procedure. The active ingredient in Lanluma (poly-L-lactic acid) has a history of clinical studies indicating its general safety in immune competent patients. But as with any treatment, there are risks.

**Contraindications and Relative Contraindications to Treatment**

Allergies or sensitivity to any of the ingredients contained in Lanluma, or in the anaesthetic applied before treatment
Hypersensitivity to lidocaine, other amide-type local anaesthetics
Use with extreme caution in patients who tend to develop hypertrophic scarring
If you are pregnant or breastfeeding
Porphyria

Limited or no clinical data exists regarding the efficacy and tolerance of this treatment in patients having a history of, or currently suffering from, auto-immune disease or auto-immune deficiency or being under immunosuppressive therapy. The clinician shall therefore decide on the indication on a case by case basis according to the nature of the disease and its treatment and the need for monitoring post-treatment. Your clinician will discuss the need for a preliminary skin testing for hypersensitivity if necessary, or in the case of patients with severe or multiple allergies. Patients on coagulation medication or other substances known to increase coagulation time must be aware of the potential increased risk of bleeding and haematoma during and following treatment.

Your clinician will also discuss the suitability of treatment having considered your medical history and any medications you currently take, as appropriate. As such, it is imperative you disclose such medications at the time of your treatment.

**Additional Information**

Most patients will achieve their desired results with between 1 to 3 treatments, usually performed at least 6 weeks apart. Your clinician will advise you on a specific treatment plan to achieve your desired results. Treatment with Lanluma is long lasting, but not permanent. The majority of patients report satisfactory results even up to 2 years after treatment. However, additional treatments may be necessary over time to produce continued results.

**Post Treatment**

Following treatment, the area injected will be massaged to assure proper distribution of the medication. It is important to continue to massage the area five times per day, for five minutes, over the subsequent five days following treatment. To decrease the possibility of a bruising event, you may also apply an ice pack to the treated area as instructed over the next 24 hours. Make up can be applied 12 hours after treatment in the absence of complications. A sunscreen with SPF30 or greater is encouraged to further minimise redness. Please ask your clinician for an after-care sheet which will give important contact details and a summary of our advice. Please do not hesitate to contact us should you have any concerns post treatment.

**Should you feel unwell following your procedure it is important to seek specialist medical advice immediately. In the first, instance call our Clinical Team on one of the following numbers. Occasionally, the phone will be directed to our emergency out of hours service who will contact Dr Curran or another member of the clinical team. Dr. John Curran can also be contacted directly in the event of an emergency or difficulty getting in contact with the clinic.**

**Jersey 01534 625090 Guernsey 01481 736699 Belfast 02890 319060 (Mon-Fri 08.00 to 17.30)**
**Dr Curran's Mobile 07781 165797**

**Consent Statement for Lanluma**

**Consent Confirmation**

To help us assess that we have listened to, and responded to, your concerns and preferences and have given you sufficient information in the way that you want and can understand it would be helpful to confirm the following statements:

1. I can confirm that I understand the treatment proposed and any relevant alternatives and I am willing to proceed.

2. I have had sufficient time to appreciate the risks involved and in particular I can confirm the clinical team/clinician has worked with me to understand and discuss those risks to which I would attach particular significance.

3. I am of the opinion that my request for treatment is for medical reasons and/or the personal psychological features that are associated with my request. I have expressed my thoughts and feelings to the treating doctor and consent to the treatment for the purpose of restoring and maintaining the health and my psychological wellbeing.

4. I have read this in conjunction with the information provided and I have had the potential risks and side effects associated with my treatment fully explained to me.

5. I acknowledge and understand that no guarantee or assurance can be made on the results I will get from the treatment.

6. I consent to the taking of photographs in the course of this procedure for the purpose of assessing my progress.

7. I am satisfied that I have sufficient knowledge of the treatment to give informed consent.

Patient has confirmed via E-Signature:

I confirm that I have discussed the treatment plan with the above patient and undertake treatment with the purpose of restoring or maintaining health, including the psychological wellbeing of my patient. I also confirm that I accept duty of care for my patient and the standard of care as set out by the GMC in Good Medical Practice/NMC Guidelines. In doing so, I recognise my primary purpose and undertaking is to place the health and wellness of my patient as my first concern.

Clinician has confirmed via E-Signature: