Information and Consent for HArmonyCa™ Injection

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

This injectable product is a sterile, apyrogenic, viscous, opaque, injectable, semi-solid, latex free and bio-degradable dermal implant. The implant is intended for sub-dermal and deep dermal use in specific facial regions for facial augmentation.

In addition to hyaluronic acid and calcium hydroxyapatite, this product contains a small amount of lidocaine. It is important to advise your clinician if you are allergic either to hyaluronic acid, calcium hydroxyapatite, or lidocaine.

Commonly Experienced Adverse Events

Redness
Swelling
Paraesthesia (nerve problems, loss of sensation, loss of motor function)
Itching
Bruising

Less Common Risks

Haematoma formation
Induration or nodules at the injection site
Staining or discolouration
Poor or weak filling effect
Infection/abscess formation
Immediate or delayed hyper sensitivity reactions to hyaluronic acid or lidocaine

Rare but serious adverse events may be associated with intra vascular injection or tissue compression which have been reported to cause temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral haemorrhage, leading to stroke, skin necrosis and/or damage to underlying structures.

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

The incidence of allergic reaction has been found to be low and as the products are non-animal based usually no test patching is required. Should your clinician have concerns about your history of allergies it may be prudent to test a small amount of product before commencing treatment.

Contraindications and Relative Contraindications to Treatment

Hypersensitivity to lidocaine, other amide-type local anaesthetics, or gram positive bacterial proteins
Untreated epilepsy
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

Depending on the volume injected, patient skin condition and age this treatment's results can last up to 12 months. Please ask your doctor to advise you regarding specific expected longevity for your treatment. Hyaluronic acid is a non-permanent treatment which is fully biocompatible, degradable and dissolvable. Patients should avoid aspirin and non-steroidal anti-inflammatory medication prior to treatment, where possible to minimise the risk of bruising. Your clinician may wish to defer treatment should you have an active cold sore lesion in the vicinity of proposed treatment.

Most treatments are relatively painless but for more superficial treatment you may require a topical anaesthetic to be applied for at least 30 minutes pre-treatment.

Post Treatment

There may be some tenderness, redness and swelling to the site, this is very normal, and this usually subsides within a few days, an ice pack can be used on the area for 24 hours after treatment to help reduce this. You should avoid strenuous activity, exposure to sunlight or tanning lamps and extreme weather conditions for 24 hours post treatment. Bruising is an occasional outcome and generally resolves. It is important to let your clinician know prior to treatment if you have important work or social engagements which may cause you embarrassment should you bruise excessively. It is recommended not to wear make up for to 12 hours post treatment in most cases. Alcohol would best be avoided for 24 hours. 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.

Consent Statement for HArmonyCa™ Injection

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 restoringand 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: