GALDERMA

EST. 1981

Restylane®

Patient Consent Form for Aesthetic Treatment

Last Name: _____ First Name: _____

Gender: _____ Date of Birth: _____ Last 4 digits of NRIC: _____

Address: _____

Mobile: _____ Email: _____

I confirm I have been informed that:

Restylane® products are sterile gels that consist of cross-linked non-animal based hyaluronic acid. Restylane® lidocaine products contain in addition 0.3% lidocaine (a local anaesthetic agent). The products are injected into the skin to correct lines, wrinkles and folds in faces, to sculpt lips and enhance facial contours. They are also used to restore elasticity of skin and reduce irregularities on the skin's surface.

My treating practitioner has explained how and when Restylane® products are used. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. In particular, I have received information regarding when treatment with Restylane® products should not take place and have also been informed of precautions, warnings for use with these products and common injection-related reactions. These reactions include redness, swelling, pain, itching, bruising and tenderness at the implant location. These reactions are generally mild to moderate and usually disappear shortly after injection. They usually resolve spontaneously a few days after injection into the skin, within a week after injection into the lips.

I have also been informed of the risks involved when injecting areas with underlying sensitive structures (e.g. nerves, vessels and eyes when treating wrinkles around eyes).

There are isolated reports of small lumps developing at the treatment sites, and irregularities that can last several months if injection into the skin is too superficial.

Inflammatory reactions have been reported in rare cases; these have consisted of redness, swelling and induration at the injection location, which can at times affect surrounding tissue. Reactions have arisen either a few days or a few weeks after treatment. They have generally been mild to moderate and self-limiting, and the average duration is two weeks. In rare cases, reactions have been recurrent and lasted for several months.

Other adverse events received from post-marketing surveillance for the use of Restylane® range of products are less common or rare, including discoloration, nodules, mass/ induration, infection/abscess, acne-like formations, granuloma, hypersensitivity reactions, ischema/necrosis, atrophy/scarring, reactions of herpes infection, rash, pruritus, telangiectasia and urticaria.

Rarely, a few people have developed infections/ inflammations that must be treated with antibiotics or other treatments.

Isolated rare cases of vision abnormalities including blindness have been reported when dermal fillers such as hyaluronic acid are used in areas around the eyes, nose and glabella.

I have been informed that Restylane® products containing lidocaine must not be used in individuals with known hypersensitivity to lidocaine or amide-type local anaesthetics. Similar to administration of dental anaesthetic, there is diminished sensation to pain and temperature in the treated area for about two hours.

My practitioner has also informed me that topical anesthetic cream might be used to have additional pain relief especially if Restylane® products without lidocaine will be injected. I have received information regarding when and what topical anesthetics will be used, and information regarding contraindications, warnings/ precautions of use of these products and potential side effects.

My treating practitioner has also informed me that, depending on the treated area and injection technique, effects from the Restylane® treatment can last 6-12 months (lips around 6 months), but this period may vary, either longer or shorter. Follow-up treatment helps maintain the desired correction.

I have responded to questions pertaining to any hypersensitivity to anaesthetic agents and to my medical history honestly. I have also received post treatment care instructions and understand the importance of following the advice and instructions given.

I have informed my practitioner of all my previous aesthetic treatments, including injections, surgeries, chemical peels etc.

I have read and understood the above and hereby consent to treatment with Restylane® products.

_____ _____

Patient's signature Date

GALDERMA

EST. 1981

I confirm that I have discussed what the procedure is likely to involve, the benefits, and risks of any available alternative treatments (including no treatment), and any concerns of this patient.

Name of Injector/Practitioner: _____

Signature of Injector/Practitioner: _____

Date: _____

Clinic Name: _____

Clinic Address:

Restylane® Abridged Information

Adapted from Restylane products' Instructions for Use.

Restylane® and Its Uses

Restylane® is a sterile, transparent, biodegradable gel of stabilized hyaluronic acid of non-animal origin. Restylane® line of products can be used for facial tissue augmentation such as correction of wrinkles, shaping the contours of the face, correction of folds and for lip enhancement and can also be used to improve the elasticity of the skin. These effects originate from the ability of stabilized hyaluronic acid to bind water.

Who should not have a Restylane® treatment?

- Patients with a known allergy to hyaluronic acid based products
- Patients with bleeding disorders or who are taking thrombolytics or anticoagulants
- Patients with active skin disease such as inflammation, infection or tumors in or near the area to be treated

Inform your doctor if:

- You are taking any medications, in particular those that affect platelet function such as aspirin and non-steroidal anti-inflammatory drugs
- You have an infection where the injection is given or if that area is swollen
- You have received previous aesthetic treatments, both surgical and non-surgical
- You are pregnant or think you may be pregnant or you are breastfeeding your baby

Additionally, for lidocaine-containing Restylane® products, inform your doctor if:

- You think you are allergic to lidocaine or to amide-type local anesthetics
- You are currently receiving lidocaine or other local anesthetics or agents structurally-related to amide-type local anesthetics
- You have any of the following medical conditions: epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction

How is Restylane® administered?

Your doctor will first disinfect the treatment area. A small amount of Restylane® is then injected into the skin through a fine needle or blunt micro-cannula to fill wrinkles or add volume, shape your face or lips or to improve your skin elasticity.

What are the possible side effects?

You may experience injection-related side effects such as bruising, redness, itching, swelling, pain or tenderness at the implant site. Typically resolution is spontaneous within a few days after injection into the skin, and within one week after injection into the lips.

The following post marketing adverse events have been reported for Restylane® fillers range:

Frequency	Side effects
Occurs in 1 in 1000 to 1 in 10,000 treatments performed	Swelling
Occurs in 1 in 10,000 to 1 in 50,000 treatments performed	Bruising, discoloration, redness, infection, inflammation, ischemia/necrosis, mass, pain/tenderness, papules/nodules
Occurs in 1 in 50,000 to 1 in 100,000 treatments performed	Hypersensitivity, hardened mass or formation, neurological symptoms such as burning or prickling sensation, itchiness, short duration of effect
Occurs in less than 1 in 100,000 treatments performed	Abscess, acne, angioedema, atrophy/scarring, blisters, capillary disorders such as spider veins, inflammation of the skin, device dislocation, abnormal connection between two body parts (fistula), granuloma, rash, reactivation of herpes infection, hives, visual disturbance

The following post marketing adverse events have been reported for Restylane® Skinboosters range:

Frequency	Side effects
Occurs in 1 in 10,000 to 1 in 50,000 treatments performed	Redness, inflammation, pain/tenderness, papules/nodules, swelling
Occurs in 1 in 50,000 to 1 in 100,000 treatments performed	Bruising, induration
Occurs in less than 1 in 100,000 treatments performed	Abscess, acne, atrophy/scarring, blisters, dermatitis, discoloration, granuloma, hypersensitivity, infection, ischemia/necrosis, mass, neurological symptoms such as burning or prickling sensation, itchiness, reactivation of herpes infection, short duration of effect, spider veins, hives

For all Restylane® line of products,

- Vascular compromise may occur due to an accidental injection into the blood vessels or as a result of vascular compression associated with implantation of any injectable product. This may manifest as blanching, discoloration, necrosis or ulceration at the implant site or in the area supplied by the blood vessels affected; or rarely as ischemic events in other organs due to embolization.
- Isolated rare cases of ischemic events affecting the eye leading to visual loss, and the brain resulting in cerebral infarction, following facial aesthetic treatments have been reported.
- Isolated rare cases of ischemia/necrosis affecting the nose have been reported after injection, especially in patients who had prior rhinoplasty.
- Symptoms of inflammation at the implant site commencing either shortly after injection or after a delay of up to several weeks have been reported.
- Post inflammatory pigmentation changes have been observed in clinical studies in people with observed in clinical studies in people with dark skin (Fitzpatrick Type IV-VI)

Additionally for Restylane® Skinboosters, in rare cases intradermal lumps have been reported to remain for several months or very rarely, longer than one year.

If you experience any serious side effects or any side effects not listed in this leaflet, please inform your doctor immediately.

Restylane®