

## **Hyaluronic Acid (HA)® INJECTION - INFORMATION FOR PATIENTS**

### **INSTRUCTIONS**

This is an informed-consent document which has been prepared to help you understand hyaluronic acid (Juvederm, Restylane, Belotero) injection, its risks, and alternative treatments. This material serves as a supplement to the discussion you have with your doctor/healthcare provider. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your doctor/healthcare professional prior to signing the consent form. It is important that you read this information carefully and completely.

**GENERAL INFORMATION** Hyaluronic acid is a substance found throughout your body in skin, as well as neural and connective tissues as well. It is a normal component of the dermis layer of skin. With aging, the dermis loses hyaluronic acid, resulting in thinning of the dermis, and lack of moisture. The causes fine lines to develop on the surface of the skin itself. The hyaluronic acid that is used for cosmetic indications is produced in the laboratory using recombinant DNA technology, so it does not come from animals, and no skin testing is required. Hyaluronic acid can be injected into the skin to add volume to areas otherwise so deficient, whether due to aging or other causes.

Fillers can be classified as temporary, semi-permanent and permanent. Temporary fillers last up to about one year, semi-permanent fillers last for a few years and permanent fillers last for the life of the patient. Although it may seem best to choose a permanent filler because it does not have to be administered again, remember that the aging process is a dynamic process and that the skin will gradually thin as aging proceeds. What may look good today may be very noticeable under the skin in five or ten years. Hyaluronic acid is a temporary filler.

### **THE TREATMENT**

Treatment with hyaluronic acid can smooth out facial folds and wrinkles, add volume to the lips, and contour facial features that have lost their volume and fullness due to aging, sun exposure, illness, etc. Facial rejuvenation can be carried out with minimal complications. These dermal fillers are injected under the skin with a very fine needle or with a blunt tip cannula. This produces natural appearing volume under wrinkles and folds which are lifted up and smoothed out. The results can often be seen immediately. Topical skin numbing preparations, super chilled air and nitrous oxide ("sweet air") are available to those who wish this to reduce the discomfort associated with injection.

**ADVISORY:** It is recommended that you not take aspirin, non-steroidal anti-inflammatory medication, or any blood anti-coagulants before this procedure. These medications may increase the risk of bruising. If you are able to stop these medications, you should do so one (1) week before the procedure.

### **PREGNANCY AND ALLERGIES**

There are no known studies examining the safety of hyaluronic acid injections during pregnancy. It is advisable not to have these injections during pregnancy until the safety of this treatment in pregnancy can be established. Hyaluronic acid is a known component in everyone's tissues, so allergy to this is not possible. However, if you have had a reaction to these injections previously, it is advisable not to have one again in the future.

### **ALTERNATIVE TREATMENTS**

Alternative forms of management include not treating the skin wrinkles and volume loss by any means. Improvement of skin wrinkles may be accomplished by other treatments or alternative types of surgery such as a blepharoplasty, face or brow lift when indicated. Minor skin wrinkling may be improved through chemical skin peels, lasers, BOTOX injections, non-hyaluronic acid fillers or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

**There is a variable amount of swelling that will occur after injection due to the characteristics of the specific hyaluronic acid preparation, and the reaction of your own tissues to the injection. Swelling is**

### **RISKS AND COMPLICATIONS**

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand risks, potential complications, limitations, and consequences of hyaluronic acid injections. Additional information concerning hyaluronic acid may be obtained from the package-insert sheets supplied by the manufacturer.

Before undergoing this procedure, understanding the risks is essential. No procedure is completely risk-free. The following risks may occur, but there may be unforeseen risks and risks that are not included on this list. Some of these risks, if they occur, may necessitate hospitalization, and/or extended outpatient therapy to permit adequate treatment. It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to: 1) Post treatment discomfort, swelling, redness, bruising, and discoloration; 2) Post treatment infection associated with any transcutaneous injection; 3) Allergic reaction; 4) Reactivation of herpes (cold sores); 5) Lumpiness, visible yellow or white patches; 6) Granuloma formation; 7) Localized necrosis and/or sloughing, with scab and/or without scab if blood vessel occlusion occurs.

The effects of the procedure typically last about 3-24 months depending upon the specific preparation selected.

The main side effects after injection are pain from injection, swelling and bruising, which are usually minimal and temporary. Localized hypersensitivity to the saline may also occur temporarily. There has never been a reported allergic reaction to hyaluronic acid.

Over or under correction of volume loss: It is possible that the result may not completely correct the volume deficiency and may require injection of additional hyaluronic acid. Similarly, the converse is also possible, in that more hyaluronic acid was injected than necessary. In some cases, hyaluronidase may be necessary to dissolve the excess filler.

**Asymmetry:** The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to hyaluronic acid injections.

**Pain:** Discomfort associated with hyaluronic acid injections is usually of short duration.

**Bleeding and Bruising:** It is possible, though unusual, to have a bleeding episode from hyaluronic acid injections. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet

inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other “herbs / homeopathic remedies” may contribute to a greater risk of a bleeding problem. Do not take these for six days before or after hyaluronic acid injections.

**Damage to Deeper Structures:** Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

**Blindness:** Blindness is extremely rare after hyaluronic acid injections. However, it can be caused by internal bleeding around the eyeball, needle stick injury or direct occlusion of blood vessels supplying blood to the eye.

**Allergic Reactions:** As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

**Infection:** Infection is extremely rare after hyaluronic acid injections. Should an infection occur, additional treatment including antibiotics may be necessary.

**Skin Disorders:** Skin rash, itching, and swelling may rarely occur following hyaluronic acid injections.

**Numbness:** Numbness of the forehead after hyaluronic acid injections is due to the local anesthetic present in the hyaluronic acid preparation. This is temporary and will abate in a few hours.

**Unsatisfactory Result:** There is the possibility of a poor result following hyaluronic acid injections. Additional BOTOX injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles and volume loss.

**Long-Term Effects:** Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss, weight gain, sun exposure, pregnancy, menopause, or other circumstances not related to hyaluronic acid injections. Hyaluronic acid injections do not arrest the aging process nor do they change the quality of the facial tissues. Future surgery or other treatments may be necessary.

**Pregnancy and Nursing Mothers:** Animal reproduction studies have not been performed to determine if hyaluronic acid injections could produce fetal harm. It is not known if hyaluronic acid can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive hyaluronic acid injection treatments.

**Intravascular injections:** The risk and consequences of accidental intravascular injection of hyaluronic acid injections is not predictable. Intravascular injection of hyaluronic acid may result in permanent blindness and/or loss of tissue due to impairment of circulation to that tissue. Should this happen, serious scarring or facial deformity can result.

**Unknown Risks:** The long-term effect of hyaluronic acid injections on tissue is unknown. There is the possibility that additional risk factors may be discovered.

**Medications and Herbal Dietary Supplements:** There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Aleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

**Travel Plans:** Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

#### **OFF-LABEL FDA ISSUES**

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is “Off-Label”, that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective. Examples of commonly accepted “Off-Label” use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes. Botox® is approved for Glabellar frown lines, Blepharospasm, and would be Off-Label for all other uses. I acknowledge that I have been informed about the Off-Label FDA status of hyaluronic acid injections, and I understand it is not experimental and accept its use.

#### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations or any resulting complications. Please carefully review your health insurance subscriber-information pamphlet. Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic surgery.

#### **ADDITIONAL TREATMENT NECESSARY**

There are many variable conditions in addition to risk and potential complications that may influence the long-term result of hyaluronic acid injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with hyaluronic acid injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

#### **RESULTS**

I am aware that when hyaluronic acid is injected into my face there is an increase in facial volume. I understand that this procedure is both an art and a science and that specific results cannot be guaranteed. I also understand that hyaluronic acid eventually will break down and the results will similarly dissipate.

#### **ALTERNATIVE PROCEDURES**

Alternatives to the procedures and options that I have volunteered for have been fully explained to me.

#### **RIGHT TO DISCONTINUE TREATMENT**

I understand that I have the right to discontinue treatment at any time.

#### **FINANCIAL RESPONSIBILITIES**

The cost of hyaluronic acid injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the hyaluronic acid material itself. It is unlikely that hyaluronic acid injections to treat cosmetic problems would be covered by your health insurance. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order

to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the injections and will also be your responsibility. In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risks and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments. I understand that this is not a medically necessary procedure and that payment is my responsibility and is expected at the time of treatment.

**DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent form for the administration of hyaluronic acid.