**ITHACA MEDICAL AESTHETICS**

Refresh \* Restore \* Rejuvenate

**Dana Gabriela Negoi, Physician, PLLC 107 N. Cayuga St., Ste 7 (607) 603-7002**

**Hyaluronidase (HYELENEX®) Consent Form for Treatment From**

To the patient: Being fully informed about your condition and treatment will help you make the decision whether or not to have a Hyaluronidase treatment. This disclosure is not to alarm you but to better inform you so that you may withhold your consent for this treatment.

Hyaluronic acid (HA) fillers are sterile gels consisting of non-animal stabilized hyaluronic acid for injection into the skin to correct facial lines, wrinkles and folds, for lip enhancement and for shaping facial contours.

Occasionally these fillers need to be dissolved when the aesthetic treatment has not produced the desired outcome or there is a possibility of vascular occlusion or impending necrosis (tissue death) which could lead to compromise of healthy tissue.

Hyaluronidase is an enzyme which breaks down hyaluronic acid fillers, but it can also break down naturally occurring hyaluronic acid present in the body, the results can be unpredictable. I understand that there will be loss of volume and there can be some skin laxity which in itself may not provide a good aesthetic result. Although some of the effects can be immediate, I understand it can take up to 24-48 hours for results to be seen and the treatment may need to be repeated.

**What are the possible side effects of hyaluronidase?**

Get emergency medical help if you have any of these **signs of an allergic reaction:** hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Less serious side effects may include pain, itching, redness, or swelling where the medication was injected. This is not a complete list of side effects and others may occur.

HYLENEX® [recombinant](https://www.rxlist.com/script/main/art.asp?articlekey=5244)is a purified preparation of the enzyme recombinant human hyaluronidase produced by genetically engineered Chinese Hamster Ovary (CHO) cells containing a DNA [plasmid](https://www.rxlist.com/script/main/art.asp?articlekey=4938)encoding for a soluble fragment of human hyaluronidase (PH20). It is used to increase the absorption and dispersion of injected drugs or to disrupt the structure of certain organs.   It is used off label to help decrease excess hyaluronic acid fillers or the Tyndall effect (blue-ish tint) which can occur if hyaluronic acid fillers are injected too superficially. I understand that this medication can be unpredictable and spread, and may dissolve all the filler that was injected.

**RISKS OF INJECTION**

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 this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your physician to make sure you understand the risks, potential complications, limitations, and consequences.  Additional information concerning Hylenex® may be obtained from the package-insert supplied by Halozyme Therapeutics, Inc.

**Bleeding and Bruising:** It is possible, though unusual, to have a bleeding episode from an injection.  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 any of these for 7 days before or after injections.

**Itching/Swelling/Pain/Redness:** Itching and swelling is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary.Discomfort associated with injections is normal and usually of short duration. Redness  in the skin occurs after injections. It can be present for a few days after the procedure.

**Infection:** Although infection is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virusinfections around the mouth can occur following treatment. This applies to both individuals with a past history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the treatment procedure in order to suppress an infection from this virus. Should any type of skin infection occur, additional treatment including antibiotics may be necessary.  Hylenex®should not be injected into or around an infected or acutely inflamed area because of the danger of spreading a localized infection.

**Pregnancy and Nursing Mothers:** It is unknown if Hylenex® can cause harm to the fetus. If you become pregnant while taking Hylenex®, discuss with your doctor the benefits and risks of using Hylenex® during pregnancy. Hylenex® does not cause problems during labor, but it is unknown if it can cause harm to the fetus during labor. It is unknown if Hylenex® is excreted in breast milk.

**Drug Interactions:** Some medicines may interact with Hylenex®. Tell your health care provider if you are taking any other medicines, especially any of the following: Local anesthetics (eg, lidocaine) because risk of side effects of Hylenex®  maybe increased;  Antihistamines (eg, diphenhydramine), certain hormones (eg, corticotropin, estrogens), cortisone, or salicylates (eg, aspirin) because the effectiveness of Hylenex® may be decreased.  Tell your doctor if you are taking benzodiazepines (eg, alprazolam), furosemide, or phenytoin because effectiveness may be decreased by Hylenex®.

**Allergic Reactions**:  In rare cases, adverse reactions to hyaluronidase have been known. The allergic reactions are quite rare, but persons with known allergies to hyaluronidase of bovine or ovine origins should not be treated with hyaluronidase. Allergic reactions may include hives, difficulty breathing, and swelling of the face, lips, tongue, or throat

**Unknown Risks:** The long term effect of Hylenex® is unknown.  The possibility of additional risk factors or complications attributable to the use of Hylenex®may be discovered.

I understand that it is not uncommon for the treated area to look “over-dissolved or pruned.” This is due to the reaction of native hyaluronic acid in the skin, which is quickly repleted and hydrated.

**DISCLAIMER**Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). 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 medical provider may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current state of medical knowledge.

**It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.**

**INFORMED CONSENT FOR HYELENEX**®**PROCEDURE or TREATMENT**

1. I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_have reviewed the information on Hyelenex and hereby authorize as may be selected by Dana Gabriela Negoi, Physician, PLLCto perform the treatment.

2. I understand what my medical provider can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

3. I understand that it is not uncommon for the treated area to look “over-dissolved or pruned.” This is due to the reaction of native hyaluronic acid in the skin, which is quickly repleted and hydrated.

4. I understand that clinical results will vary per patient.

5. I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and /or court cost and reasonable legal fees, should this be required. No refunds will be given for treatments received.  Health insurance companies may not pay for Hyelenex injections for cosmetic reasons.  Please carefully review your health insurance subscriber information pamphlet.

6. I understand that the fees charged for this procedure do not include any potential future costs for additional procedures that I elect to have or require in order to revise, optimize, or complete my outcome. Additional costs may occur should complications develop from the injections and will be my responsibility.  In signing the consent, I acknowledge that I have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

7. I have read and understand the Pre and Post-Treatment Instructions. I agree to follow these instructions carefully. I understand that compliance with recommended pre and post procedure guidelines are crucial for healing, prevention of side effects and complications as listed above.

8. I consent to be photographed or televised before, during, and after the procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

9. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

10. I acknowledge that I have been informed that some of the treatment may be “Off-label”.  I understand that it is not experimental and accept its use.

11.I have disclosed all my medical history and medications to Dana Gabriela Negoi, Physician, PLLC. I am currently not taking any of the following medications.

a) Furosemide (Lasix)

b) Phenytoin (Dilantin)

c) A sedative or anxiety medication (such as Valium, Xanax)

d) Aspirin or salicylates5) Cortisone or ACTH (Corticotropin)

e) Estrogens

f) An antihistamine (such as a cold or allergy medicine)

12. I acknowledge that I will have to remain at the clinic for thirty minutes after the procedure so that I can be observed by the practitioner and that I may need to return to the clinic in 1-2 weeks after treatment to assess if further hyaluronidase is to be administered.

The use of and the indications for the administration of hyaluronidase have been explained to me by Dana Gabriela Negoi, Physician, PLLC. and I have had the opportunity to have all questions answered to my satisfaction. After the treatment some other common injection-related reactions might occur. These reaction may include redness, swelling, pain, itching, bruising and tenderness at the injection site. They have generally been described as mild to moderate and typically resolve spontaneously a few days after injection.

I have read the above and understand it. I consent to the administration of hyaluronidase (HYELENEX®). I am satisfied with the explanation. My questions have been answered satisfactorily by Dana Gabriela Negoi, Physician, PLLC. If I have any questions or problems after treatment I will call Dana Gabriela Negoi, Physician, PLLC. I have been provided with their contact information. I accept the risks and complications of the procedure.

Patient Name (Print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Witness Name (Print)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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