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Informed Consent for Botulinum Toxin Type A Injection

Instructions

This is an informed consent document which has been prepared to help us inform you concerning BOTOX or Jeuveau or other Botulinum Toxin A brand injection, its risks, and alternative treatments. It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure. The word BOTOX in this consent will be used as a general name that can include other types of Botulinum Toxin Type A as well as the brand name BOTOX.

Introduction

Clostridia botulinum bacteria produce a class of chemical compounds known as “toxins”. The Botulinum Type A Toxin (BOTOX) is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis (chemodenervation) of the muscle by preventing transmission of nerve impulses to the muscle. The duration of muscle paralysis generally lasts for approximately three months.

BOTOX has been used to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), and motor disorders of the facial nerve (VII cranial nerve). It has been used in other “off-label” uses for the treatment of facial wrinkles and neck bands caused by specific muscle groups.

BOTOX injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region, forehead, and neck. BOTOX cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. Botox injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles 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. Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion). Minor skin wrinkling may be improved through chemical skin-peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

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Risks of Botox (Botulinum Type A Toxin) Injections

Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. 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 complications, you should discuss each of them with your provider to make sure you understand the risks, potential complications, and consequences of BOTOX injections.

Bleeding- It is possible, though unusual, to have a bleeding episode from a BOTOX injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BOTOX injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Do not take any aspirin or anti-inflammatory medications for seven days before and after BOTOX injections, as this may contribute to a greater risk of a bleeding problem.

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.

Corneal exposure problems- Some patients experience difficulties closing their eyelids after BOTOX injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.

Dry eye problems- Individuals who normally have dry eyes may be advised to use special caution in considering BOTOX injections around the eyelid region.

Migration of BOTOX- BOTOX may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects.

Drooping Eyelid (Ptosis)- Muscles that raise the eyelid may be affected by BOTOX, should this material migrate downward from other injection areas. Eyedrops can be given to improve this problem.

Double vision- Double vision may be produced if the BOTOX material migrates into the region of muscles that control movements of the eyeball.

Eyelid Ectropion- Abnormal looseness of the lower eyelid can occur following BOTOX injections.

Other eye disorders- Functional and irritative disorders of eye structures may rarely occur following BOTOX injections.

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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 BOTOX injections.

Life-Altering Headaches/Pain- Discomfort associated with BOTOX injections is usually short duration. However, rarely permanent severe headaches may occur after BOTOX injections.

Skin disorders- Skin rash and swelling may rarely occur following BOTOX injections.

Unsatisfactory result- There is a possibility of a poor or inadequate response from BOTOX injection. Additional BOTOX injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity. Any and all additional injections are the financial responsibility of the patient.

Respiratory- On rare occasions, some have some have experienced bronchitis or sinusitis.

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

Antibodies to BOTOX- Presence of antibodies to BOTOX may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BOTOX is unknown.

Infection- Infection is extremely rare after BOTOX injections. Should an infection occur, additional treatment including antibiotics may be necessary.

Long-term effects- Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to BOTOX injections. BOTOX injection does not arrest the aging process or produce permanent tightening of the eyelid region. Future surgery or other treatments may be necessary.

Pregnancy and nursing mothers- Animal reproduction studies have not been performed to determine if BOTOX could produce fetal harm. It is not known if BOTOX can be excreted in human milk.

Blindness- Blindness is extremely rare after BOTOX injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. The occurrence of this is very rare.



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Drug interactions- The effect of BOTOX may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Unknown risks- The long term effect of BOTOX on tissues is unknown.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long term result of BOTOX injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BOTOX 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.

Financial Responsibilities

The cost of BOTOX injections may involve several charges. Additional costs of medical treatment would be your responsibility. Should complications develop from BOTOX injections. Rarely more BOTOX may be necessary to accomplish the desired result. Additional injections are the financial responsibility of the patient.

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The risks, benefits, and alternatives of the procedure(s) were explained to me. I understand the specific risks in the consent material for my procedure and understand the significant risks that may occur. I understand the anticipated results and I have realistic expectations. I agree to follow all instructions and to notify the office if any problems or questions arise.

- I certify that I have none of the known conditions that would contraindicate treatment. These conditions include hypertrophy scars, a history of any autoimmune disease, or immune therapy. I am not pregnant, breast-feeding, and I have no known allergy to BOTOX.
- I certify that I have read this entire informed consent and that I understand and agree to information stated in this form. I certify that I am a competent adult of at least 18 years of age, or that I am a minor under the age of 18, I understand that the consent of my parent/legal guardian will also be required before treatment. This informed consent is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors, and assigns. I agree that any picture taken of my treatment site may be used for publication and teaching purposes, however, my name will not be disclosed and complete confidentiality of my name will be maintained.
- I understand that the results are of temporary nature, and more treatments will be needed to maintain improvement. I agree to adhere to all safety precautions described here including:
 - No laying down or reclining for four hours after injection
 - No scratching or rubbing the injected area
 - No bending forward for four hours

By signing below I certify that I have read and understand the above Informed Consent Material for my specific procedure.

Patient Signature:

Date

Witness:

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Client Questionnaire

Name: _____

Date: _____

Date of Birth: _____

Medical Information:

NO YES

<input type="checkbox"/>	<input type="checkbox"/>	Allergies- History of severe allergy or anaphylaxis
<input type="checkbox"/>	<input type="checkbox"/>	Recently taken Aspirin or Ibuprofen. If yes, when?
<input type="checkbox"/>	<input type="checkbox"/>	Diagnosed with an Autoimmune disease, HIV, Lupus, or Hepatitis
<input type="checkbox"/>	<input type="checkbox"/>	Bruise or cut easily
<input type="checkbox"/>	<input type="checkbox"/>	Currently pregnant or breast feeding
<input type="checkbox"/>	<input type="checkbox"/>	History of Keloid scarring
<input type="checkbox"/>	<input type="checkbox"/>	Currently on immunosuppressive therapy
<input type="checkbox"/>	<input type="checkbox"/>	Currently tanning or using a tanning booth
<input type="checkbox"/>	<input type="checkbox"/>	History of oral herpes (fever blisters)
<input type="checkbox"/>	<input type="checkbox"/>	Currently under the care of a physician
<input type="checkbox"/>	<input type="checkbox"/>	Currently taking any medications, including OTC medications and Herbal supplements taken regularly- if yes, please list:
<input type="checkbox"/>	<input type="checkbox"/>	Any other medical or skin condition not listed above- if yes, please list:

Reviewed by: _____ Date: _____