BOTULINA TOXINS - BOTOX® INJECTION - INFORMATION FOR PATIENTS

INSTRUCTIONS

This is an informed-consent document which has been prepared to help you understand BOTOX® (Botulina Toxin Type A, Allergan) 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

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The Botulina 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 muscle by preventing transmission of nerve impulses to muscle. The duration of muscle paralysis generally lasts for approximately three to four months.

BOTOX has been approved to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder with the neck) and motor disorders of the facial nerve (VII cranial nerve). As of April 2002, it has been FDA-approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups. Other areas of the face and body such as crows feet wrinkles and neck bands may be treated in an "off-label" fashion. BOTOX has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

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.

THE TREATMENT

Botox® (Botulinum Toxin type A) is the only FDA approved treatment for the temporary reduction of moderate to severe forehead lines and wrinkles, frown lines and crow's feet. It is accomplished by injecting small amounts of Botox® solution in the area of the wrinkles. Botox® works by temporarily relaxing the facial muscles that are responsible for producing the wrinkling of the facial skin, thus producing the appearance of smoother, flatter skin.

Botulinum toxin (Botox® and similar agents) is a neurotoxin produced by the bacterium Clostridium A. Botulinum toxin can relax the muscles on areas of the face and neck which cause wrinkles associated with facial expressions or facial pain. Treatment with botulinum toxin can cause your facial expression lines or wrinkles to be less noticeable or essentially disappear. Areas most frequently treated are: a) glabellar area of frown lines, located between the eyes; b) crow's feet (lateral areas of the eyes); c) forehead wrinkles; d) radial lip lines (smokers lines), e) head and neck muscles. Botox is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. Patients may feel a slight burning sensation while the solution is being injected. The procedure takes about 5 - 10 minutes and the results can last up to 3 months. With repeated treatments, the results may tend to last longer.

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.

Patients with certain medical conditions may not have this procedure done. These include those with any type of facial paralysis such as Bell's palsy, Guillain-Barre Syndrome and Myasthenia Gravis. Patients who are pregnant or breastfeeding should not use Botox®.

PREGNANCY, ALLERGIES & NEUROLOGIC DISEASE
I am not aware that I am pregnant and I am not trying to get pregnant, I am not lactating (nursing). I do not have any significant neurologic disease including but not limited to myasthenis gravis, multiple sclerosis, lambert-eaton syndrome, amyotrophic lateral sclerosis (ALS), and Parkinson's. I do not have any allergies to the toxin ingredients, or to human albumin.

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.

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 BOTOX injections. Additional information concerning BOTOX may be obtained from the package-insert sheets supplied by Allergan.

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.

The effects of the procedure typically last about 3-5 months. Be advised that it is possible for a patient to experience some adjacent facial muscle relaxation in areas other than the intended target muscle. Most common is the effect of ptosis, or eyelid droop. This condition occurs in less than 3% of injections. It is temporary and will usually resolve before the Botox® wears off.

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 BOTOX.

Incomplete Block: It is possible to not experience a complete block of desired muscles. Additional injections to reach the desired level of block can be performed until the goal is achieved.

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.
Drooping Eyelid (Ptosis): Muscles that raise the eyelid may be affected by BOTOX, should this material migrate downward from other injection areas.
Pain: Discomfort associated with BOTOX injections is usually of short duration.
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. BOTOX has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).
Bleeding and Bruising: 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. 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 BOTOX 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.
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.
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.
Blindness: Blindness is extremely rare after BOTOX injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In a period of 10 years of BOTOX administration, complications of blurred vision, retinal vein occlusion, and glaucoma have been reported in three patients. The occurrence of eye problems appears to be very rare.
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.
Skin Disorders: Skin rash, itching, and swelling may rarely occur following BOTOX injection.
Neuromuscular Disorders: Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk of clinically significant side effects from BOTOX.
Numbness: Numbness of the forehead after BOTOX injection has been reported.
Headache: A transient headache after BOTOX injection may occur.
Flu-like symptoms: Flu-like symptoms may occur after BOTOX injection.
Migraine Headache Disorders: BOTOX has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of BOTOX treatments for migraine headaches may be variable and improvement in this disorder may not occur following BOTOX treatments.
Unsatisfactory Result: There is the possibility of a poor or inadequate response from BOTOX injections. Additional BOTOX injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.
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 BOTOX injections. BOTOX injections do 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. It is not recommended that pregnant women or nursing mothers receive BOTOX treatments.
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 tissue is unknown. The risk and consequences of accidental intravascular injection of BOTOX is unknown and not predictable. 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 Botox®, 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 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.

RESULTS
I am aware that when small amounts of purified botulinum toxin are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 2 – 10 days and usually lasts up to 3 months but can be shorter or longer. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual and there are some individuals who do not respond at all. I understand that I will not be able to use the muscles injected as before while the injection is effective but that this will reverse after a period of months at which time re- treatment is appropriate. I understand that I must stay in the erect posture and that I must not manipulate the area (s) of the injections for the 2 hours post-injection period.

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 BOTOX 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 BOTOX material itself. It is unlikely that BOTOX 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 BOTOX.

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