Informed Consent Form

Botox Cosmetic (onabotulinumtoxin A)
Dysport (abobotulinumtoxin A)
Xeomin (incobotulinumtoxin A)

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about BOTOX® (*Botulina* Toxin Type A, Allergan) injections, its risks, as well as alternative treatment(s).

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 as proposed by your provider and agreed upon by you.

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 and more recently approved for treatment of crow's feet wrinkles as of September 2013. Other areas of the face and body such as smoker's lines around the lips 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.

INDICATIONS

BOTOX® (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used:

- To treat leakage of urine (incontinence) in adults 18 years and older with overactive bladder due to neurologic disease who will still have leakage or cannot tolerate the side effects after trying an anticholinergic medication.
- To prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years and older with upper limb spasticity.
- To treat increased muscle stiffness in elbow, wrist, and finger muscles in people 18 years and older with upper limb spascity.
- To treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 16 years and older.
- To Treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX® is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough in 18 years and older.
It is not known whether BOTOX® is safe or effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).
It is not known whether BOTOX® is safe or effective to treat increased stiffness in upper limb muscles other than those in the elbow, wrist, and fingers or to treat increased stiffness in lower-limb muscles. BOTOX® has not been shown to help people perform task-specific functions with their upper limbs or increase movement in joints that are permanently fixed in position by stiff muscles. Treatment with BOTOX® is not meant to replace your existing physical therapy or other rehabilitation that your doctor may have prescribed.
It is not known whether BOTOX® is safe or effective for severe sweating anywhere other than your armpits.

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.

INHERENT RISKS OF BOTOX (BOTULINA TYPE A TOXIN) INJECTIONS

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 Medical Provider 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.

SPECIFIC RISKS OF BOTOX (BOTULINA TYPE A TOXIN) INJECTIONS

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 injection.

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 ten 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.

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.

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 injection.

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 injection. 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, and motor neuropathies) may be at greater risk of clinically significant side effects from BOTOX.

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 treatment 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 injection. 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 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. 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

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 provider believes it to be safe and effective.

Authorization (s):

_____ (Patient Initials) — I acknowledge that I have been informed about the Off-Label FDA status of BOTOX® (*Botulina* Toxin Type A, Allergan) and I understand it is not experimental and accept its use.

_____ (Patient Initials) — Pregnancy and Neurologic disease; I attest that I am not pregnant and I am not breastfeeding (Female patients only), nor that I have any significant neurologic disease. Furthermore, I agree to keep my treatment Provider informed should I become pregnant or become diagnosed with a neurologic disease during the course of treatment.

_____ (Patient Initials) — Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction

_____ (Patient Initials) — I understand that the procedure is purely elective, that the results may vary with each individual, and multiple treatments may be necessary.

_____ (Patient Initials)

Infection is possibility anytime a skin procedure is performed or the skin surface is disrupted. Keeping the treated area clean is important. If signs of infection develop after your treatment, such as pain, heat, blisters, or surrounding redness, please call our office immediately. If you have ever had, currently have, or develop a cold sore or herpes outbreak during the course of treatment, IT IS YOUR RESPONSIBILITY TO NOTIFY YOUR TREATMENT PROVIDER IMMEDIATELY.

_____ (Patient Initials)

Medical History: I have given a complete history of all medical conditions, previous surgeries and treatments, current list of all medications and allergies. I agree to notify my treatment Provider immediately of any changes to my medical history during the course of my treatments. I understand that any failure to do so may affect the results of my treatment and/or increase the likelihood of side effects or post-treatment complications.

_____ (Patient Initials)

Post-treatment instructions: I have been advised that treatment results should be seen 4-7 days 4-7 days after the treatment. I have also been advised to maintain an erect posture and that I must refrain from strenuous exercise, nor manipulate the injection sites for at least twelve (12) hours post-treatment.

_____ (Patient Initials)

Photographs: Photographic documentation may be taken. I hereby do _____do not_____ authorize the use of my photographs for teaching purposes.

_____ (Patient Initials)

I acknowledge that it has been recommended to avoid anti-inflammatory meds (such as Ibuprofen, Motrin, Advil, green tea, vitamin E, and Ginko Biloba to reduce possible side effects of bruising and swelling in the areas of treatment. Blood thinning meds may also cause these side effects. Anyone who bruises or bleeds easily, as well as bleeds heavily and/or has questions about their meds or their condition may wish to consult your Medical Provider prior to treatment. It is also recommended to avoid alcoholic drinks before receiving Botox A injections (s).

_____ (Patient Initials)

have read and understand all information presented to me before consenting to treatment.

_____ (Patient Initials)

I have had all my questions answered. I freely consent to the proposed treatment.

I _____, hereby authorize (provider's name) _____

_____to perform Botox Cosmetic, Dysport, or Xeomin Injection on me.

_____ _____

PATIENT SIGNATURE DATE TIME

AND/OR

_____ _____

RESPONSIBLE RELATIVE OR GUARDIAN RELATIONSHIP

_____ _____

PROVIDER'S NAME PROVIDER'S SIGNATURE