

Perez Neurology

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P E R E Z N E U R O L O G Y

Botulinum Toxin Consent Form

Botulinum toxin has been approved by the Federal Drug Administration for treatment of chronic migraine. Botulinum toxin does not cure chronic migraine and it may not be effective in some patients. There have, however, been no serious injuries or deaths resulting from its use for this indication.

The administration of botulinum toxin is accomplished by injecting a small amount of toxin into the muscles of the head and neck. Dosage must be titrated for each individual. Any benefits resulting from botulinum toxin tend to wear off after about 3 months with a repeat injection required if benefit is to be maintained.

Injections are usually done every 3 to 4 months with a maximal effect peak achieved by about 2-3 weeks.

The side effects of botulinum toxin used for chronic migraine may include:

- Temporary, and usually mild, facial weakness with facial injections
- Temporary, and usually mild, head or neck weakness with head/neck injections
- Reduction or loss of forehead facial animation due to forehead muscle weakness
- Eyelid drooping (ptosis)
- Temporary pain at the site of the injection or ecchymosis (black and blue mark) at the site of injection
- Temporary dry eye
- Temporary double vision

It is also possible that as with any injection, there may be an allergic reaction or no effect from the medication. Reduced effectiveness after repeated injections is sometimes seen and rarely infection at the injection site may occur. There is the possibility of potential unknown risks associated with this treatment. Care will be taken to prevent these side effects. If therapy is given over a long time, atrophy and wasting in the muscle injected may occur.

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

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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 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 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.

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.

INFORMED CONSENT – BOTULINA TOXINS - BOTOX® INJECTION

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

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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 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.

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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.

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.

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GENERAL RISKS

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection: Infection is unusual after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infections in other parts of the body, may lead to an infection in the operated area.

ADDITIONAL ADVISORIES

Female Patient Information: It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Most people have lightly swollen pinkish bumps where the injections went in, for a couple of hours or even several days.

Although many people with chronic headaches or migraines often get relief from Botox/Xeomin/Myobloc, a small percent of patients get headaches following treatment, for the first day. In a very small percentage of patients these headaches can persist for several days or weeks.

Local numbness, rash, pain at the injection site, flu like symptoms with mild fever, back pain.

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Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.

Bruising is possible anytime you inject a needle into the skin. This bruising can last for several hours, days, weeks, months and in rare cases the effect of bruising could be permanent.

While local weakness of the injected muscles is representative of the expected pharmacological action of Botox, weakness of adjacent muscles may occur as a result of the spread of the toxin.

Treatments: I understand more than one injection may be needed to achieve a satisfactory result.

I will follow all aftercare instructions as it is crucial I do so for healing.

As Botox, Xeomin and Myobloc are not exact sciences, there might be an uneven appearance with some muscles more affected by the Botox than others. In most cases this uneven appearance can be corrected by injecting Botox in the same or nearby muscles. However in some cases this uneven appearance can persist for several weeks or months.

This list is not meant to be inclusive of all possible risks associated with Botox/Myobloc as there are both known and unknown side effects associated with any medication or procedure.

Botox, Xeomin and Myobloc should not be administered to a pregnant or nursing woman.

Additionally, the number of units injected is an estimate of the amount of Botox/Xeomin/Myobloc required to paralyze the muscles.

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I understand there is no guarantee of results of any treatment.

I understand the regular charge applies to all subsequent treatments.

I agree that I am of sound mind and have read the above information and consent to the administration of botulinum toxin at this time and for on-going treatment, as required.

Patient Consent _____ Date _____

Witness Consent _____ Date _____

Witness Consent _____ Date _____