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Informed Consent –BOTOX® / DYSPORT ®/ XEOMIN® Injection for

INSTRUCTIONS

This is an informed-consent document which has been prepared to help your plastic surgeon and the nurse injectors in his/her office inform you concerning BOTOX® (*Onabotulinumtoxin A*) , DYSPORT® (*Abobotulinumtoxin A*), and /or XEOMIN® (*Incobotulinumtoxin A*) injections, the potential risks, and the 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 as proposed by your plastic surgeon 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, DYSPORT, or XEOMIN) 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, although it may vary among individuals, and no guarantees can be made about your response time.

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.

DYSPORT has been approved to treat cervical dystonia (spastic muscle disorder with the neck). As of April 2009, 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. DYSPORT has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

XEOMIN was approved by the FDA for similar indications in July of 2011, and became available in physicians' offices early in 2012.

BOTOX, DYSPORT AND XEOMIN 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, DYSPORT and XEOMIN cannot stop the process of aging. They can, however, temporarily diminish the look of wrinkles caused by muscle groups. BOTOX, DYSPORT and XEOMIN injections may be performed as a single procedure or as an adjunct to a surgical procedure.

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CONTRAINDICATIONS

DO NOT HAVE TREATMENT if you have shown an allergic reaction to *any* of the Botulinum products in the past, including Myobloc, Botox, Dysport, or Xeomin.

Consult with your doctor if you have shown an allergic reaction to any of the inactive ingredients, in order to select a product that does not contain your allergen.

Do not have *Dysport* treatment if you are allergic to cow's milk protein.

The ingredients in BOTOX are:
Active ingredient: botulinum toxin Type A.
Inactive ingredients: human albumin and sodium chloride.

The ingredients in DYSPORT are:
Active ingredient: botulinum toxin Type A
Inactive ingredients: human albumin and lactose. **Dysport may contain cow's milk protein**.

The ingredients in XEOMIN are:
Active ingredient: botulinum toxin Type A
Inactive ingredients: human albumin, sucrose.

Regarding Human Albumin and Transmission of Viral Diseases:

These products contain albumin taken from human plasma. Steps taken during donor screening and product manufacturing processes make the risk of spreading viral diseases extremely rare. In theory, there is also an extremely rare risk of contracting Creutzfeldt-Jakob disease (CJD). No cases of spread of viral diseases or CJD have ever been reported for albumin.

The proteins from the whites of eggs are collectively referred to as album *en*. Ovalbumin the principal protein of egg albumen, is a different protein from human serum albumin.

DO NOT HAVE TREATMENT if you have a skin infection at the planned injection site.

DO NOT HAVE TREATMENT until you tell your doctor about all your medical conditions, especially if you: have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome).

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 lifts 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 of BOTOX, DYSPORT & XEOMIN (Botulinum Type A Toxin) Injections

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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, DYSPORT & XEOMIN injections. Additional information concerning BOTOX, DYSPORT, and XEOMIN may be obtained from the package-insert sheets supplied by the manufacturers.

The FDA requires the use of this "Black Box Warning" in a discussion of the cosmetic application of these products even though the warnings are much more applicable to the therapeutic use of these agents in the medical conditions noted above:

IMPORTANT SAFETY INFORMATION

Distant Spread of Toxin Effect
Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of Botox/Botox Cosmetic at the labeled dose of 20 units (for glabellar lines) or 100 units (for severe primary axillary hyperhydrosis) have been reported.

Bleeding and Bruising- It is possible, though unusual, to have a bleeding episode from a BOTOX / DYSPORT / XEOMIN injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BOTOX / DYSPORT / XEOMIN 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 / DYSPORT /XEOMIN 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 / DYSPORT / XEOMIN 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 / DYSPORT/ XEOMIN injections around the eyelid region.
Migration of Botulinum Toxin- BOTOX / DYSPORT / XEOMIN may migrate from the original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. BOTOX / DYSPORT / XEOMIN have been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).
Drooping Eyelid (Ptosis) - Muscles that raise the eyelid may be affected by botulinum toxin, should this material migrate downward from other injection areas.
Double-Vision- Double-vision may be produced if the botulinum toxin material migrates into the region of muscles that control movements of the eyeball.
Eyelid Ectropion- Abnormal looseness of the lower eyelid can occur following botulinum toxin injection.
Other Eye Disorders- Functional & irritative disorders of eye structures may rarely occur following botulinum toxin injections.

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Blindness- Blindness is extremely rare after botulinum toxin 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.

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 botulinum toxin injection.

Pain- Discomfort associated with botulinum toxin injections is usually of short duration.

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

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

Infection- Infection is extremely rare after botulinum toxin injection. Should an infection occur, additional treatment including antibiotics may be necessary.

Skin Disorders- Skin rash, itching, and swelling may rarely occur following botulinum toxin 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 botulinum toxin.

Migraine Headache Disorders- botulinum toxin has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of botulinum toxin treatment for migraine headaches may be variable and improvement in this disorder may not occur following botulinum toxin treatments.

Unsatisfactory Result- There is the possibility of a poor or inadequate response from botulinum toxin injection. Additional BOTOX / DYSPORT /XEOMIN 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 botulinum toxin injections. BOTOX/ DYSPORT/ XEOMIN 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 / DYSPORT / XEOMIN could produce fetal harm. It is not known if BOTOX / DYSPORT / XEOMIN can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BOTOX / DYSPORT /XEOMIN treatments.

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

Unknown Risks- The long-term effect of botulinum toxin on tissue is unknown. The risk and consequences of accidental intravascular injection of botulinum toxin is unknown and not predictable. There is the possibility that additional risk factors may be discovered.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of Botox/Botox Cosmetic at the labeled dose of 20 units (for glabellar lines) or 100 units (for severe primary axillary hyperhydrosis) have been reported.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

ADDITIONAL TREATMENT NECESSARY

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

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DYSPORT / XEOMIN material itself. It is unlikely that BOTOX / DYSPORT / XEOMIN 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 of medical treatment would be your responsibility should complications develop from BOTOX / DYSPORT /XEOMIN injections. **In signing the consent for this surgery/procedure, you acknowledge that your have been informed about the risks and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

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). 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 of the facts pertaining to 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 on the next page.

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CONSENT FOR PROCEDURE or TREATMENT

1. I, , hereby authorize Dr. Riolo and such assistants as may be selected to perform the following procedure or treatment:

   BOTOX / DYSPORT / XEOMIN INJECTION
   (list the anatomic areas where BOTOX / Dysport will be injected i.e. frontalis and corrugator muscles)

   _____

   I have received the following information sheet:
   INFORMED CONSENT – BOTOX / DYSPORT / XEOMIN INJECTION

2. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.

4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.

5. I consent to be photographed or televised before, during, and after the operation(s) or 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.

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

7. I realize that not having the treatment is an option.

8. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
   a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
   b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
   c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I, CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-10). I AM SATISFIED WITH THE EXPLANATION.

_____
Patient or Person Authorized to Sign for Patient

Date_____ _____Witness

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