

# INFORMED CONSENT FOR BOTOX COSMETIC®, DYSPORT®, XEOMIN® INJECTION

PATIENT'S NAME \_\_\_\_\_  
(PLEASE REVIEW AND BRING WITH YOU ON THE DAY OF YOUR PROCEDURE)

**Before considering treatment with Botulinum Toxin A (BTA), I state that to the best of my knowledge, I do NOT have any of these conditions:**

- Diseases that affect muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome)
- Allergies to any botulinum toxin product
- Allergies to cow's milk products (Dysport only)
- Allergies to human serum albumin products (Xeomin only)
- Any past side effects from BTA (Botox, Dysport, Xeomin, MyoBlock)
- Serious breathing problem, such as asthma or emphysema
- Swallowing problems or inhaling food or fluid into your lungs (aspiration)
- Pregnancy or active breast feeding

## **INSTRUCTIONS**

Being fully informed about your condition and treatment will help you make the decision whether or not to undergo treatment with botulinum toxin type A (BTA). This disclosure is not meant to alarm you; it is simply an effort to better inform you so that you may give or withhold your consent for this treatment. 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 healthcare provider.

## **INTRODUCTION**

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The BTA 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 months. BTA 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. Certain spastic muscle disorders with the neck and colorectal area have also been treated with this agent. BTA 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. BTA cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups.

## **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 of BTA (Botulinwn Toxin A) 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 BTA injections.

Bleeding- It is possible, though unusual, to have a bleeding episode from a BTA injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BTA 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 two days before BTA 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 BTA 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 BTA injections around the eyelid region.

Migration of BTA- BTA 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 BTA, should this material migrate downward from other injection areas.

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

Eyelid Ectropion- Abnormal looseness of the lower eyelid can occur following BTA injection.

Other Eye Disorders- Functional and irritative disorders of eye structures may rarely occur following BTA injections.

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 BTA injection.

Pain- Discomfort associated with BTA injections is usually short duration.

Skin disorders- Skin rash and swelling may rarely occur following BTA injection.

Unknown risks-The long-term effect of BTA on tissue is unknown. There is the possibility of additional risk factors may be discovered.

Unsatisfactory result-There is the possibility of a poor or inadequate response from BTA injection. Additional BTA injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

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

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

Infection- Infection is extremely rare after BTA injection. 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 of gain, sun exposure, or other circumstances not related to BTA injections. BTA 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 BTA could produce fetal harm. It is not known if BTA can be excreted in human milk.

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

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

Non-FDA Approved Uses- We use only FDA approved products purchased directly from the manufacturer. However, the injections sites may be different than those approved by the FDA.

### **RESULTS**

I understand that the amount (number of units) injected is an estimate of the amount of BTA required to paralyze the muscles in order to get a desired result. I understand the results are of temporary nature, and more treatments will be needed to maintain improvement. I also understand there is no guarantee of results of any treatment. Furthermore, I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and/ or Court cost and reasonable legal fees, should this be required.

### **ADDITIONAL TREATMENT NECESSARY**

There are many variable conditions in addition to risk and potential complications that may influence the long term result of BTA injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BTA 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 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 material itself. It is unlikely that injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from filler injections.

### **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 provider may provide you with additional or different information, which is based on all of the facts pertaining to your particular case and the 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.**

CONSENT FOR PROCEDURE

1. I hereby authorize employees and assistants as may be selected to perform the following procedure or treatment:

Botox, Dysport, Xeomin Injection

I have received the following information sheet:  
INFORMED-CONSENT for BTA Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. I consent to the photographing or televising of the 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.
4. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
5. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
  - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
  - h. 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 (1-5). I AM SATISFIED WITH THE EXPLANATION.

Patient Name (please Print)

\_\_\_\_\_

Patient Signature

\_\_\_\_\_

date \_\_\_\_\_

Witness Signature

\_\_\_\_\_

date \_\_\_\_\_