AUDUBON DERMATOLOGY
INNOVATIVE COMPREHENSIVE SKINCARE

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Botox, Dysport, & Xeomin Informed Consent

BOTOX® Cosmetic (OnabotulinumtoxinA)
DYSPORT® (AbobotulinumtoxinA)
XEOMIN®(IncobotulinumtoxinA)

Being fully informed about your condition and treatment will help you make the decision whether or not to undergo BOTOX/DYSPORT/XEOMIN treatment. 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.

I have requested that Dr. Hooper or Dr. Jackson attempt to improve my facial lines with BOTOX/DYSPORT/XEOMIN. These injections have been used for more than a decade to improve spasm of the muscles around the eye, to correct double vision due to muscle imbalance as well as numerous other neurological uses. BOTOX/DYSPORT/XEOMIN is now approved by the FDA to improve the appearance of the vertical lines between the brows. A few tiny injections of BOTOX/DYSPORT/XEOMIN relax overactive muscles and soften those vertical lines. Injections in other areas to improve appearance of facial lines have been reported in the literature, but the FDA has not approved those uses. The results of BOTOX/DYSPORT/XEOMIN are usually dramatic, although the practice of medicine is not an exact science and no guarantees can be or have been made concerning expected results. No refunds will be given for treatments received.

The BOTOX/DYSPORT/XEOMIN solution is injected with a tiny needle into the muscle; you should see the benefits develop over the next 2-14 days. A decreased appearance of frowning or creasing of other lines will be the result of this treatment.

BOTOX® Cosmetic (onabotulinumtoxinA) Important Information Indication

BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in patients 18 to 65 years of age.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

Distant Spread of Toxin Effect

Post marketing 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.

CONTRAINDICATIONS

BOTOX® Cosmetic is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with
known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

WARNINGS

The recommended dosage and frequency of administration for BOTOX® Cosmetic should not be exceeded. Risks resulting
from administration at higher dosages are not known.

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX® Cosmetic are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX® Cosmetic cannot be compared to or converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Spread of Toxin Effect

Please refer to Boxed Warning for Distant Spread of Toxin Effect.
No definitive, serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX®
Cosmetic at the labeled dose of 20 Units (for glabellar lines) have been reported.

Injections In or Near Vulnerable Anatomic Structures

Care should be taken when injecting in or near vulnerable anatomic structures. Serious adverse events including fatal outcomes have been reported in patients who had received BOTOX injected directly into salivary glands, the oro-lingualpharyngeal region, esophagus and stomach. Some patients had pre-existing dysphagia or significant debility. (Safety and effectiveness have not been established for indications pertaining to these injection sites.) Pneumothorax associated with injection procedure has been reported following the administration of BOTOX near the thorax. Caution is warranted when injecting in proximity to the lung, particularly the apices.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional
disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given
botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including
severe dysphagia and respiratory compromise from typical doses of BOTOX® Cosmetic.

Human Albumin

This product contains albumin, a derivative of human blood. Based on effective donor screening and product
manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for

transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS

Caution should be used when BOTOX® Cosmetic treatment is used in patients who have an inflammatory skin problem at the injection site, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin, or the inability to substantially lessen glabellar lines by physically spreading them apart.

Information for Patients

Patients should be counseled that if loss of strength, muscle weakness, or impaired vision occur, they should avoid driving a car or engaging in other potentially hazardous activities.

Drug Interactions

Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like nondepolarizing blockers, lincosamides, polymyxins, quinidine, magnesium sulfate, anticholinesterases, succinylcholine chloride) should only be performed with caution as the effect of the toxin may be potentiated.The effect of administering different botulinum neurotoxin serotypes at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Pregnancy

Administration of BOTOX® Cosmetic is not recommended during pregnancy. There are no adequate and well-controlled studies of BOTOX® Cosmetic in pregnant women.

Nursing Mothers

It is not known whether BOTOX® Cosmetic is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BOTOX® Cosmetic is administered to a nursing woman.

ADVERSE REACTIONS

General

The most serious adverse events reported after treatment with botulinum toxin include spontaneous reports of death,
sometimes associated with anaphylaxis, dysphagia, pneumonia, and/or other significant debility.

There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. The most frequently reported adverse events following injection of BOTOX® Cosmetic include blepharoptosis and nausea.

BOTOX Cosmetic have the highest risk of getting these problems.

2. Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away
from the injection site
and cause symptoms of a serious condition called botulism. The symptoms of botulism include:

- loss of strength and muscle weakness all over the body
- double vision
- blurred vision and drooping eyelids
- hoarseness or change or loss of voice (dysphonia)

- trouble saying words clearly (dysarthria)
- loss of bladder control
- trouble breathing
- trouble swallowing

These symptoms can happen hours, days, to weeks after you receive an injection of **BOTOX** or **BOTOX Cosmetic**.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving **BOTOX** or **BOTOX Cosmetic**?"

There has not been a confirmed serious case of spread of toxin effect away from the injection site when **BOTOX** has been used at the recommended dose to treat chronic migraine, severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX Cosmetic** has been used at the recommended dose to treatfrown lines.

What should I tell my doctor before taking BOTOX or BOTOX Cosmetic?

Tell your doctor about all your medical conditions, including if you:

Do not take **BOTOX** or **BOTOX Cosmetic** if you:

- are allergic to any of the ingredients in **BOTOX** or **BOTOX Cosmetic**. See the end of this Medication Guide for a list of ingredients in **BOTOX** and **BOTOX Cosmetic**.
- had an allergic reaction to any other botulinum toxin product such as *Myobloc®, Dysport®, or Xeomin®*
- have a skin infection at the planned injection site
- are being treated for urinary incontinence and have a urinary tract infection (UTI)
- 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). See "What is the most important information I should know about **BOTOX** and **BOTOX Cosmetic**?"
- have allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- have or have had a breathing problem, such as asthma or emphysema
- have or have had swallowing problems
- have or have had bleeding problems
- have plans to have surgery
- had surgery on your face
- have weakness of your forehead muscles, such as trouble raising your eyebrows
- have drooping eyelids
- have any other change in the way your face normally looks
- have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence.

Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever.

- have problems emptying your bladder on your own and are being treated for urinary incontinence
- are pregnant or plan to become pregnant. It is not known if **BOTOX** or **BOTOX Cosmetic** can harm your unborn baby.
- are breast-feeding or plan to breastfeed. It is not known if **BOTOX** or **BOTOX Cosmetic** passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines,
vitamins and herbal products. Using **BOTOX** or **BOTOX Cosmetic** with certain other medicines may cause
serious side effects. **Do not start any new medicines until you have told your doctor that you have received**
BOTOX or BOTOX Cosmetic in the past.
Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin, such as *Myobloc®* (rimabotulinumtoxinB), *Dysport®* (abobotulinumtoxinA), or *Xeomin®* (incobotulinumtoxinA) in the past. Be sure your doctor knows exactly which product you received.
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine
- take anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners)

The most common side effects are headache, respiratory infection, flu syndrome, temporary eyelid droop, and nausea. BOTOX/DYSPORT/XEOMIN should not be used if there is an infection near the injection site. Additionally, slight temporary bruising may occur at the injection site. I have been advised of the risks involved in such treatment, the expected benefits of such treatment, and alternative treatments, including no treatment at all.

I understand that the results are temporary and several sessions may be needed for optimal results.

If you choose to have topical anesthesia applied all risk associated with topical anesthesia are possible including allergic reaction, swelling, irritation, and in large quantities overdose which can result in death.

I understand and agree that all services rendered to me are charged to me directly and that I am personally responsible for payment.

I am not pregnant or trying to become pregnant nor am I nursing at this time.

I agree that this constitutes full disclosure, and that it supersedes any previous verbal or written disclosures. I certify that I have read, and fully understand, the above paragraphs, and that I have had sufficient opportunity for discussion and to ask questions. I consent to this BOTOX/DYSPORT/XEOMIN treatment today and for all subsequent treatments.

I release Audubon Dermatology, LLC, Dr. Hooper, Dr. Jackson and all medical staff, from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Client's Name (Please Print):_____

Client's Signature:_____

Date:_____ Time:_____