Botulinum Toxin Type A: Botox® Cosmetic & Dysport® Consent Form

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 adult patients ≤ 65 years of age

BOTOX® Cosmetic (onabotulinumtoxinA) for injection, is a sterile, vacuum-dried purified botulinum toxin type A, produced from fermentation of Hall strain Clostridium botulinum type A grown in a medium containing casein hydrolysate, glucose, and yeast extract, intended for intramuscular use. BOTOX® Cosmetic blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine. This inhibition occurs as the neurotoxin cleaves SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. When injected intramuscularly at therapeutic doses, BOTOX® Cosmetic produces partial chemical denervation of the muscle resulting in a localized reduction in muscle activity.

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

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DYSPORT™ (abobotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients.

The effects of DYSPORT™ and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. 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, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

DYSPORT™ is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation. This product may contain trace amounts of cow's milk protein. Patients known to be allergic to cow's milk protein should not be treated with DYSPORT™.DYSPORT™ is contraindicated for use in patients with infection at the proposed injection site(s).

There are no adequate and well-controlled studies in pregnant women. DYSPORT™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether DYSPORT™ is excreted in human milk.

I authorize and direct \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **(Injector)** to perform the following procedure of

Botox® Cosmetic and/or Dysport® injections on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (**patients name**) for

the treatment of (areas to be treated):

* Glabella Initials:\_\_\_\_\_\_\_\_\_\_\_
* Forehead Initials:\_\_\_\_\_\_\_\_\_\_\_
* Crows Feet Initials:\_\_\_\_\_\_\_\_\_\_\_
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please initial the following:**

\_\_\_\_\_\_\_\_The details of the procedure have been explained to me in terms I understand.

\_\_\_\_\_\_\_\_Alternative methods and their benefits and disadvantages have been explained to me.

\_\_\_\_\_\_\_\_I understand that the FDA has only approved the cosmetic use of Botox® Cosmetic and Dysport® for frown lines between the brows. Any other cosmetic use is considered off label.

\_\_\_\_\_\_\_\_I understand and accept the most likely risks and complications of Botox® Cosmetic and Dysport® injections.

Including but not limited to:

* Paralysis of a nearby muscle that could interfere with opening of eye(s).
* Local numbness
* Headache, nausea, or flu-like symptoms
* Swallowing, speech, or respiratory disorders
* Swelling, bruising, or redness at the injection site
* Disorientation and double vision
* Temporary asymmetrical appearance
* Abnormal or lack of facial expression
* Inability to smile when injected in the lower face
* Facial pain
* Product ineffectiveness

\_\_\_\_\_\_\_\_I understand and accept that the long-terms effects of repeated use of Botox® Cosmetic and Dysport® injections are unknown. Possible risks and complications that have been identified, but are not limited to:

* Muscle Atrophy
* Nerve irritability
* Production of antibodies with unknown effect to general health

\_\_\_\_\_\_\_I understand and accept the less common complications, including the remote risk of death or serious disability that exists with this procedure.

\_\_\_\_\_\_\_I am aware that smoking during the pre and post-procedure periods could increase chances of complications.

\_\_\_\_\_\_\_I have informed the doctor or nurse of all my known allergies, including any allergies to latex.

\_\_\_\_\_\_\_I have informed the doctor or nurse of all medications I am currently taking including prescriptions, OTC remedies, herbal therapies, and any other.

\_\_\_\_\_\_\_I have been advised whether I should take any or all of the medications on the days surrounding the procedure.

\_\_\_\_\_\_\_I am aware and accept that no guarantees regarding the result of this procedure have been made or implied.

\_\_\_\_\_\_ I understand that the medical professional, my injector will recommend the amount of product that he/she believes is appropriate for the results that I desire. If I choose not to accept that recommendation, I understand that I may not achieve the desired result and any further treatments to achieve the desired result will require full payment.

\_\_\_\_\_\_ Prices are subject to change. The pricing I receive during this treatment is only for today's treatment. Any additional treatments, products or services will be billed at rates in effect at time of the additional treatments.

\_\_\_\_\_\_I have been informed of what to expect post-treatment, including but not limited to procedures I can do if I wish to maintain the appearance that this procedure provides me.

\_\_\_\_\_\_I am not currently pregnant or nursing, and I understand that should I become pregnant while using Botox® Cosmetic and Dysport® there are risks, including fetal malfunction.

\_\_\_\_\_\_I consent to photographs being taken for use in the following areas: evaluation of treatment, effectiveness, medical training and education, marketing, media stories, advertising and other sales purposes. No photographs revealing my identity will be used without my written consent. If my identity is not revealed (by name), these photographs may be used and displayed publically without my permission.

\_\_\_\_\_\_If pre and post-treatment photos and/or video are taken of the treatment for record purposes, I understand that these photos will be the property of the attending doctor or nurse.

\_\_\_\_\_\_The doctor and/ or nurse has answered all my questions regarding this procedure.

\_\_\_\_\_\_I have been advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

\_\_\_\_\_\_\_ I certify that I have read and understand this agreement and that all spaces for initials were filled in PRIOR to my signature.

**Patient Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_ I certify that I have explained the nature, purpose, benefits, risks, complications, and alternatives of the proposed procedure to the patient. I have answered fully, and I believe that the patient fully understands what I have explained.

**Nurse Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_