MEDICAL AESTHETICS
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DYSPORT® CONSENT FORM

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INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you concerning DYSPORT® (abobotulinumtoxinA) injections, its risks, and alternatives treatments(s).

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 as proposed by your provider and agreed upon by you.

GENERAL INFORMATION

DYSPORT® 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 less than 65 years of age.

DYSPORT® injections involve a series of small subcutaneous injections designed to weaken certain muscles that cause skin wrinkling. Weakening of the injected muscles begins to be apparent after 2-3 days with the peak effect being reached after 7-14 days. Results can last 3-6 months. The procedure can be repeated after 3 months; however, injections given at less than 3 month intervals may not produce a noticeable effect.

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 fillers or fat, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

INHERENT RISKS OF BTA 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. Although the majority of patients do not experience these complications, you should discuss each of them with your provider to make sure you understand risks, potential complications, limitations, and consequences of DYSPORT® injections. Additional information concerning DYSPORT® may be obtained from the package-insert sheets supplied by Galderma Laboratories.

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as Myobloc®, Xeomin®, or Botox® in the past (tell your doctor 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 aspirin-like products or blood thinners.

SPECIFIC RISKS OF DYSPORT® (abobotulinumtoxinA) INJECTIONS

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that 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 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 in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

*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®

SWALLOWING AND BREATHING DIFFICULTIES:

Treatment with DYSPORT® and other botulinum toxin products can result in, dry mouth, swallowing or breathing difficulties. Patients with preexisting swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing.

UPPER RESPITORY DIFFICULTIES:

Reports of nasopharyngitis, upper respiratory tract infection and sinusitis have occurred. Incomplete Result: It is possible to not experience a complete result of targeted muscles. Additional injections to reach the desired level of result 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 BTA injection.

DROOPING EYELID (PTOSIS):

Muscles that raise the eyelid may be affected by BTA, should this material migrate downward from other injection areas. Should this problem occur, it is temporary and additional treatments such as eye drops may be necessary.

PAIN:

Discomfort associated with BTA injections is usually of short duration.

MIGRATION OF BTA:

BTA may migrate from its original injection site to other areas and produce temporary weakness of other muscle groups or other unintended effects. BTA has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the neck region (cervical dystonia).

BLEEDING AND BRUISING:

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, you 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 BTA injections. If you are taking these medications, please inform your provider prior to proceeding.

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.

UNKNOWN RISKS:
The long-term effect of BTA on tissue is unknown. The risk and consequences of accidental intravascular injection of BTA 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 BTA injections around the eyelid region.

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 irritive disorders of eye structures may rarely occur following BTA injections.

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 eye problems appears to be very rare.

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 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.

SKIN DISORDERS:
Skin rash, itching, and swelling may rarely occur following BTA 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 BTA.

MIGRAINE HEADACHE DISORDERS:
Headaches are possible and usually last one day but may persist longer in a very small percentage of patients. Patients are advised that results of BTA treatment for migraine headaches may be variable and improvement in this disorder may not occur following BTA treatments.

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. Unsatisfactory results may NOT improve with each additional treatment.

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 BTA injections. BTA injection does not stop the aging process or produce permanent tightening of skin. 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. It is not recommended that pregnant women or nursing mothers receive BTA treatments. Please inform your provider prior to proceeding if you are pregnant or think you could be or if you are nursing.

DRUG INTERACTIONS:

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

ADDITIONAL ADVISORIES:

Medications and Herbal Dietary Supplements: There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix, Warfarin, Coumadin, Xarelto, Effient or Pradaxa, discuss management of these medications around the time of treatment with your provider. If you have an adverse reaction, stop the drugs immediately and call your provider for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

SUN EXPOSURE – DIRECT OR TANNING SALON:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their provider and either delay treatment, or avoid tanning until the provider says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

IMPORTANT COMMITMENTS/TRAVEL PLANS:

Any treatment holds the risk of complications that may delay healing and your return to normal life. Please let the provider know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of treatment can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

FEMALE PATIENT INFORMATION:

It is important to inform your provider if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant.

MENTAL HEALTH DISORDERS AND ELECTIVE TREATMENT:

It is important that all patients seeking to undergo elective treatment have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional treatment and often are stressful. Please openly discuss with your provider, prior to treatment, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may

benefit psychologically from the results of elective treatment, effects on mental health cannot be accurately predicted.

OFF-LABEL FDA ISSUES:

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is "Off-Label", that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your provider believes it to be safe and effective.

PATIENT COMPLIANCE:

Follow all physician instructions carefully; this is essential for the success of your outcome. Personal and vocational activity needs to be restricted.

DISCLAIMER:

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including a decision not to proceed with treatment.

This document is based on a thorough evaluation of scientific literature and relevant clinical practices to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. The informedconsent 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 the facts in 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.

AUTHORIZATION (S):

_____ (Patient Initials) I acknowledge that I have been informed about the Off-Label FDA status of DYSPORT® (abobotulinumtoxinA) and I understand it is not experimental and accept its use.

_____ (Patient Initials) For women: I confirm that I am not pregnant and do not intend to become pregnant anytime during the course of treatment.

_____ (Patient Initials) Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.

_____ (Patient Initials) I understand tha t the procedure is purely elective, that the results may vary with each individual, and multiple treatments may be necessary.

_____ (Patient Initials) I have read and understand all information presented to me before consenting to treatment.

_____ (Patient Initials) I have had all my questions answered. I freely consent to the proposed treatment.

_____ (Patient Initials) Photographic documentation will be taken for teaching and before/after purposes. I hereby □ do □ do not authorize the use of my photographs and understand that all attempts will be made to conceal my identity.

I, _____ hereby authorize _____ to perform DYSPORT® injection on me. I understand that I am a patient of Medical Aesthetics MA, a medical practice led by a Harvard trained Board Certified Plastic Surgeon with over two decades of medical aesthetic experience, and that my licensed provider is an employee of the practice.

PATIENT SIGNATURE DATE TIME

and/or

RESPONSIBLE RELATIVE OR GUARDIAN RELATIONSHIP

PROVIDER'S NAME PROVIDER'S SIGNATURE