

## BOTOX (Botulinum A Toxin) INFORMED CONSENT

I, \_\_\_\_\_, understand that I will be injected with Botulinum A Toxin (Botox), Dysport, and/or Xeomin in the area of the glabella muscles to paralyze these muscles temporarily or in the forehead or crow's feet around the lateral area of the eyes.

Botulinum A Toxin (Botox), Dysport, and/or Xeomin injection has been FDA approved for use in the cosmetic treatment for glabellar frown lines only – the wrinkles between the eyebrows. I understand that other areas such as forehead muscles or crow's feet are considered off label use.

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 the procedure as proposed.

### THE TREATMENT

Botulinum toxin (Botox<sup>®</sup> and similar agents) is a neurotoxin produced by the bacterium Clostridium A. Botulinum toxin can relax the muscles on areas of the face and neck which cause wrinkles associated with facial expressions or facial pain. Treatment with botulinum toxin can cause your facial expression lines or wrinkles to be less noticeable or essentially disappear. Areas most frequently treated are: a) glabellar area of frown lines, located between the eyes; b) crow's feet (lateral areas of the eyes); c) forehead wrinkles; d) radial lip lines (smokers lines), e) head and neck muscles. Botox is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. Patients may feel a slight burning sensation while the solution is being injected. The procedure takes about 15-20 minutes and the results can last 4-6 months. With repeated treatments, the results may last longer.

Injection of Botulinum A Toxin (Botox), Dysport, and/or Xeomin into the small muscles between the brows causes those specific muscles to halt their function (be paralyzed), thereby improving the appearance of the wrinkles. I understand the goal is to decrease the wrinkles in the treated area. This paralysis is temporary, and re-injection is necessary within four to six months. It has been explained to me that other temporary and more permanent treatments are available.

### RISKS

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 an elective procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience any complications, you should discuss each of them with your doctors to make sure you understand risks, potential complications, limitations, and consequences of BOTOX injections. Additional information concerning BOTOX may be obtained from the package-insert sheets supplied by Allergan.

**The possible side effects of Botulinum A Toxin (Botox), Dysport, and/or Xeomin include but are not limited to:**

1. Incomplete Block: It is possible to not experience a complete block of desired muscles. Additional injections to reach the desired level of block can be performed until the goal is achieved.
2. There is a risk of swelling, rash, headache, local numbness, pain at the injection site, bruising, respiratory problems, and allergic reaction.
3. Infections can occur which in most cases are easily treatable but in rare cases a permanent scarring in the area can occur.
4. Most people have lightly swollen pinkish bumps where the injections went in, for a couple of hours or even a few days.
5. Although many people with chronic headaches or migraines often get relief from Botulinum A Toxin (Botox), Dysport, and/or Xeomin, a small percent of patients get headaches following treatment with Botox, for the first day. In a very small percentage of patients these headaches can persist for several days or weeks.
6. Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.
7. 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 BOTOX injections.
8. While local weakness of the injected muscles is representative of the expected pharmacological action of Botulinum A Toxin (Botox), Dysport, and/or Xeomin, weakness of adjacent muscles may occur as a result of the spread of the toxin.
9. Dry Eye Problems: Individuals who normally have dry eyes may be advised to use special caution in considering BOTOX injections around the eyelid region
10. Neuromuscular Disorders: Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk of clinically significant side effects from BOTOX.
11. Unsatisfactory Result: There is the possibility of a poor or inadequate response from BOTOX injections. Additional BOTOX injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.
12. 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 BOTOX injections. BOTOX injections do not arrest the aging process or produce permanent tightening of the eyelid region.

13. **Treatments:** I understand more than one injection may be needed to achieve a satisfactory result.
14. Another risk when injecting Botulinum A Toxin (Botox), Dysport, and/or Xeomin around the eyes included corneal exposure because people may not be able to blink the eyelids as often as they should to protect the eye. This inability to protect the eye has been associated with damage to the eye as impaired vision, or double vision, which is usually temporary. There are medications that can help lift the eyelid, however, if the drooping is too great the eye drops are not that effective. These side effects can last for several weeks or longer. This occurs in 2-5 percent of patients.
15. *I will follow all aftercare instructions as it is crucial I do so for healing.*

**Mental Health Disorders and Elective Surgery:** It is important that all patients seeking to undergo elective surgery 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 doctor, 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 surgery, effects on mental health cannot be accurately predicted.

**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 doctor and avoid tanning for 1 week before and after treatment. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

As Botulinum A Toxin (Botox), Dysport, and/or Xeomin is not an exact science, there might be an uneven appearance of the face with some muscles more affected by the Botox than others. In most cases this uneven appearance can be corrected by injecting Botox in the same or nearby muscles. However, in some cases this uneven appearance can persist for several weeks or months.

This list is not meant to be inclusive of all possible risks associated with Botulinum A Toxin (Botox), Dysport, and/or Xeomin as there are both known and unknown side effects associated with any medication or procedure.

Botulinum A Toxin (Botox), Dysport, and/or Xeomin should not be administered to a pregnant or nursing woman.

Additionally,

The number of units injected is an estimate of the amount of Botulinum A Toxin (Botox), Dysport, and/or Xeomin required to paralyze the muscles. I understand there is no guarantee of results of any treatment. I understand the regular charge applies to all subsequent treatments.

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.

By signing below, I acknowledge that I have read the foregoing informed consent and agree to the treatment with its associated risks. I hereby give consent to perform this and all subsequent Botulinum A Toxin (Botox), Dysport, and/or Xeomin treatments with the above understood. I hereby release the doctor, the person injecting the Botulinum A Toxin (Botox), Dysport, and/or Xeomin and the facility from liability associated with this procedure.

Initial \_\_\_\_\_

### PREGNANCY, ALLERGIES & NEUROLOGIC DISEASE

I am not aware that I am pregnant and I am not trying to get pregnant, I am not lactating (nursing). I do not have any significant neurologic disease including but not limited to myasthenic gravis, multiple sclerosis, lambert-eaton syndrome, amyotrophic lateral sclerosis (ALS), and Parkinson's. I do not have any allergies to the toxin ingredients, or to human albumin.

Initial \_\_\_\_\_

### ALTERNATIVE PROCEDURES

Alternatives to the procedures and options that I have volunteered for have been fully explained to me.

Initial \_\_\_\_\_

### PAYMENT

I understand that this is an "elective" procedure and that payment is my responsibility and is expected at the time of treatment.

Initial \_\_\_\_\_

### RIGHT TO DISCONTINUE TREATMENT

I understand that I have the right to discontinue treatment at any time.

Initial \_\_\_\_\_

### PHOTOGRAPHY

If Pre and Post-Treatment photos and/or videos are taken of the treatment for record purposes; I understand that these photos will be property of CARE ESTHETICS®. I understand that these photos may be used for diagnostic, educational, advertising, scientific/teaching purposes, or record keeping purposes. I waive my rights to any royalties, fees and to inspect the finished production as well as advertising materials in conjunction with these photographs.

Initial \_\_\_\_\_

## RESULTS

I am aware that when small amounts of purified botulinum toxin are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 2 – 10 days and usually lasts up to 4-6 months but can be shorter or longer. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual and there are some individuals who do not respond at all. I understand that I will not be able to use the muscles injected as before while the injection is effective but that this will reverse after a period of months at which time re-treatment is appropriate. I understand that I must stay in the erect posture and that I must not manipulate the area (s) of the injections for the 2 hours post-injection period.

Initial \_\_\_\_\_

I understand this is an elective procedure and I hereby voluntarily consent to treatment with botulinum toxin injections for facial dynamic wrinkles, TMJ dysfunction, bruxism or various types of orofacial pain including headaches and migraines. The procedure has been fully explained to me. I also understand that any treatment performed is between me and the doctor/healthcare provider who is treating me and I will direct all post-operative questions or concerns to the treating clinician. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure and I understand that no guarantees are implied as to the outcome of the procedure. I also certify that if I have any changes in my medical history, I will notify the doctor/healthcare professional who treated me immediately. I also state that I read and write in English.

Initial \_\_\_\_\_

## CONSENT

Your consent and authorization for this procedure is strictly voluntary. By signing this consent form, you hereby grant authority to the doctor to have Botox injections of your choice for any related treatment as may be deemed medically necessary or advisable in the treatment areas you so choose. The nature and purpose of this procedure, with possible alternative methods of treatment as well as complications, have been fully explained to my satisfaction.

No guarantee has been given as to the results that may be obtained by this treatment. I have read this informed consent form and certify that I understand its contents in full. I have had enough time to consider this information and I feel that I can sufficiently advise to consent to this procedure. I hereby give my consent to this procedure and have been asked to sign this form after being fully informed of the risks and benefits involved.

Initial \_\_\_\_\_

The details of this procedure have been explained to me in terms of:

- Alternative methods and their benefits and disadvantages have been explained to me.
- I am aware that smoking during the pre and post-operative periods could increase chances of complications.
- I have informed the doctor or nurse of all my known allergies, including allergies to latex.
- I have informed the doctor or nurse of all medications I am currently taking including prescriptions, over the counter medications/remedies, herbal therapies and any other.
- I am aware and accept that no guarantees regarding the result of this procedure have been made or implied.
- 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 effective at time of the additional treatments.
- I am not currently pregnant or nursing.
- 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 prior to my signature

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**Patient Name (Print)**

**Patient Signature**

**Date**