

CONSENT FOR BOTOX OR DYSPORT TREATMENT

Dr Michael McGuiness

This document is presented for you to read prior to your treatment with Botox and/or Dysport (B/D). It is informational, and should assist in helping you more fully understand treatment with B/D, including some of the associated risks, benefits, alternative treatments, and the actual treatment process. Together with information you may have obtained elsewhere, this document will help you make an informed decision about whether you actually want to be treated with B/D or not. You have the right to read this consent form completely prior to your proposed treatment with B/D, to ask any questions you may have about the treatment, and to have your questions answered to your satisfaction before receiving any treatment with B/D.

Please tell us before treatment with B/D, if you have ever had surgery of any type, especially cosmetic surgery such as a facelift, browlift, or eye surgery, to your face, scalp, ears or neck. Prior surgery of these types, could significantly affect the proper planning for your treatment and/or your response to your B/D treatment. We also should know if you have been treated previously with B/D or “fillers”, and if so, when this last took place.

What are Botox and Dysport (B/D) B/D are toxins produced by a bacterium called Clostridium. The toxin produced by Clostridium is notorious for being the cause of “botulism”, a potentially fatal disease. It was found that this same toxin, when injected in very small amounts into muscles, caused the muscle to be paralyzed temporarily. (Some people like to say the muscles are “relaxed” or “weakened”) When the toxin is metabolized by your body and gone in a few months, the muscle is able to move again, just as it was prior to being injected with B/D. Corporate America has found ways to produce these toxins in sterile, purified form, that have been able to be used safely in humans for many medical conditions, and cosmetic purposes, since the 1980’s.

Purpose/Benefit of Botox and Dysport B/D, for our purposes, are used to minimize/correct/decrease certain lines in the face and neck, that are made by the contraction of certain muscles. After the B/D is injected into a muscle, it becomes unable, or much less able, to move/contract over the next 1-14 days. By decreasing the movement/contraction of certain muscles, certain lines in the skin can be decreased very noticeably, at least until the B/D wears off in 3-5 months. When certain lines in the skin (particularly between the eyebrows, crows feet, and forehead) are decreased significantly, it is thought by many observers, that the face appears more youthful, rested, and less angry looking. Such subjective improvements in the facial appearance are very pleasing to many patients, and are often accompanied by increased self confidence, social standing, and workplace stature.

Proposed Treatment The treatment proposed today is injecting small amounts of Botox or Dysport into certain muscles (specified later in this consent document) for the purpose of weakening these muscles and severely decreasing their ability to contract. It is expected that this will lead to significant lessening of certain lines of the face and or neck that are usually made by the movement of these muscles.

Risks and Complications of Treatment With Botox or Dysport

The following list is not intended to be complete or exhaustive. It outlines the major and/or most common potential risks and complications. Other risks and complications, known and unknown do exist, and could occur.

1 - The Black Box Warning

The FDA, since 2009, has required Botox and Dysport to include, in their package insert, a section called the “black box warning”. This warning is found on many other drugs very different from B/D. A drug is required to have this warning in its informational package insert, if it has been shown in some way that use of the drug is associated with potential serious side effects, including death. Botox has been shown to cause death, severe respiratory depression requiring being put on a breathing machine, and digestive problems requiring a feeding tube. These occurrences happened in almost all cases, in patients receiving Botox for serious medical problems like cerebral palsy, or movement disorders, where large amounts of Botox were needed, and injected deep into tissue. Unfortunately, in a small number of these patients, the Botox migrated far away from its intended site of action, leading to these unfortunate and severe side effects. Thus, the black box warning for Botox, and all medications like Botox that have subsequently been developed and utilized in medicine, like Dysport.

However, the FDA also stated that when Botox is used in very small amounts, superficially, for cosmetic purposes, that the risk of such side effects is probably zero. In reality, when B/D are used for cosmetic purposes, in small amounts, and injected into superficial muscles, the risk of any major side effect, such as death, breathing problems or major swallowing problems, is indeed, this side of zero. The data from numerous studies and millions of B/D treatments over the past 20 years, support this point without equivocation.

2 – asymmetry/drooping. B/D are microscopic molecules mixed with water, and injected with precision, into muscles, to weaken them, which in almost all cases gives a pleasing result. However, it must be appreciated that these injections are mostly *water*, and even under the best of circumstances, once injected, there is a possibility that the water, with the B/D in it, could migrate, even just a bit, to an area that was not intended. Further, although the anatomy of the human body is known pretty well, no two people have exactly the same anatomy including the size, and position of their muscles. If, for some reason, the B/D ends up partially in a location not intended, there is a possibility that the B/D could affect the muscles injected, or adjacent muscles, in a way that could lead to asymmetry in appearance, either at rest, or with muscle movement. Depending on the body locations injected, there are several adverse outcomes, including but not limited to: drooping of eyelids or eyebrows; crooked smile; crooked frown; double vision; inability to purse lips; difficulty swallowing. Sometimes these adverse effects are short lived i.e. a few weeks, while other times they may last the full duration of the B/D i.e. months. When B/D are injected by skilled people with good experience, these adverse outcomes are very uncommon, but they do uncommonly happen. Please take this into consideration if you have important social or professional functions shortly after the time you are planning on getting B/D injections. Remember though, the results of treatment with B/D, (almost always very good – on rare occasions not so good) are completely reversible over time.

3 – on a rare occasion, the treatment with B/D does not work, works to a much lesser degree than is usual, or lasts for a much shorter period of time than expected. Again, these outcomes are very uncommon, but are probably most commonly seen in patients getting B/D treatment for the first or

second time. This is due to not knowing if either Botox or Dysport just don't work in someone (rare), or getting the appropriate dose of B/D right. Some people need more or less than the "average" amount of B/D for the best results, but this may take a couple treatments to optimize.

4 – pain. B/D are injected via a syringe and needle which punctures the skin. This could cause pain, though it is usually very minimal. When the B/D are actually being injected into the muscle(s), some people report a bit of "burning", but again, this is usually very minimal if it occurs.

5 – headache is a rare side effect, but if it occurs, could be severe. It could last several days. It is unpredictable who might get a headache from B/D treatment. Interestingly, B/D are indicated for the treatment of some headaches. If you get a headache with either Botox or Dysport, you often do not get a headache with the other.

6 – swelling at the sites of injection are common and usually go away in an hour or less. Be aware, these small, short lived, injection site swellings are very recognizable to other people who have had treatment with BD, as an obvious sign of BD treatment.

7 – bruising/bleeding can be expected on occasion, since injections are being placed in muscles, which have a lot of blood vessels. If this occurs, it is usually small and resolves in several days in most cases. Any medication that thins the blood and decreases its ability to clot, including prescription or non prescription medications, and herbal or holistic compounds that thin the blood, should be stopped for one week prior to BD injections, to minimize bleeding and bruising, if possible. *Not stopping these products for at least one week prior to treatment with B/D definitely increases your risk of significant, noticeable bleeding and bruising. Always check with your doctor before stopping any prescribed or recommended blood thinning medication however.* (common blood thinning products include aspirin, Advil, Motrin, ibuprofen, warfarin, Coumadin, Plavix, alcohol, vitamin E, and several homeopathic products.)

Also, if you have an innate, naturally occurring problem with easy or "free" bleeding, please inform us prior to treatment with B/D.

8 – itching at or near the B/D injection sites for a few minutes to hours is possible, but uncommon.

9 – redness at the B/D injection sites is common, but usually is gone within a few minutes to an hour.

10 – infection is a very rare possibility, but anytime the skin is punctured, the possibility exists.

11 – muscle twitching after B/D injections is rare, as is numbness, but anytime a needle is put into the body, a nerve may be injured, leading to some type of adverse symptom.

12 – patient disappointment could occur, if the results do not meet expectations. We make every effort, including through the use of this consent form, to present realistic expectations of what patients should expect after B/D treatment. In the great majority of cases, patients experience noticeable results with which they are very pleased. Perfection is not promised, not is it a realistic expectation.

Anticipated Benefits of Botox and /or Dysport Treatment

Injection of B/D into specific muscles causes those muscles to become weak, with significantly decreased movement. Certain lines of the face and neck are caused by the movement or contraction of these muscles. When these muscles are unable to move after B/D injection, the lines of the face and neck caused by the movement of these muscles are usually dramatically decreased. (lines/creases in the face and neck, which are present at rest, are much less likely to respond to treatment with B/D, or respond much less so, compared with lines that appear, or are more noticeable when muscles contract) Significant reduction in severity of lines of the face and neck is usually thought of as aesthetically pleasing and attractive to the patient, as well as to the patients friends, family, coworkers, and independent observers. The response to B/D treatment usually begins in 1-5 days, and is fully in place by about two weeks. The effect on the muscles by B/D typically lasts between 3-5 months, at which time, the muscles will become fully functional again, and the lines caused by the movement of these muscles will also reappear. Repeat treatment with B/D will lead to the same results as the previous

treatment. If B/D treatments are done at regular intervals, timed so that the muscles are treated before regaining full function, it is possible that the time interval needed between B/D treatments will gradually increase. It may take more than one treatment to achieve the goals desired with B/D. The final results will not be known until after one or more treatments. Again, perfection is not a reasonable goal, but noticeable improvement (meaning decreased visibility or prominence of facial/neck lines and wrinkles) is. Sometimes, although rare, results may not meet the expectations of the patient, despite the best efforts of all involved.

How to Care for Areas Treated With Botox and/or Dysport

- do not rub the area where B/D was injected for at least 4 hours. This could lead to spread of B/D to other areas, and increased side effects
- it may be helpful to contract and relax the muscles injected with B/D for a half hour or so after treatment. It is thought this may help the muscle absorb the B/D more quickly, leading to quicker onset of action, and less chance of movement to unwanted areas.
- Do not workout for at least 4 hours after treatment with B/D. This includes weightlifting, any cardio activity, sports, Pilates, yoga.
- Try and stay upright for at least 4 hours after treatment.
- Failure to comply with these recommendations may lead to increased side effects, and adverse or suboptimal results.

Limitations and Alternatives to Botox and/or Dysport Treatment

B/D are best at treating lines and wrinkles made by the movement of muscles. Lines and wrinkles present at rest are less likely to respond as well. Treatments with B/D may not work, or work less than expected, or last for a shorter time than expected. Alternative approaches to treating lines and wrinkles with B/D include chemical peels, laser treatment, photodynamic therapy, topical creams, surgical treatments such as a facelift or browlift, and injection of fillers such as Juvederm and Restylane, and of course, no treatment at all.

Other Conditions That We Should Know About Before Treating You With Botox or Dysport

If you have had B/D treatments in the past or treatment with fillers of any type, please tell us before we treat you, especially if you experienced any problems.

If you are pregnant, or not actively avoiding pregnancy, or breast feeding, you should not get treatment with B/D.

If you have any significant neurological disease, you should tell us before treatment. Some neurologic conditions such as Parkinsons disease, ALS (Lou Gehrigs disease), myasthenia gravis, multiple sclerosis, previous stroke, or Bells palsy, among others, may make you a poor candidate for treatment with B/D.

Again, if you have had any type of surgery to the head or neck, especially cosmetic surgery, please tell us before your B/D treatment. This knowledge is important in planning your treatment, and could affect your response to B/D treatment.

Follow Up Visits After Treatment With Botox and/or Dysport

There may be times that your medical provider will want to have you come back to the office after treatment with B/D for a post treatment evaluation. Please keep this appointment if one is suggested, as it is important for good care.

Do not hesitate to contact us if you have questions or problems after your B/D treatment. You should understand that if you seek medical assistance outside of our office for any problems or questions, that you will be responsible for any cost incurred.

Costs of Treatment with Botox and/or Dysport

Treatment with B/D in our office for the purpose of improving the appearance, is considered cosmetic, and as such is not covered by insurance. You are responsible for the entire fee associated with B/D treatment. An estimate of the cost will be made in writing to you prior to treatment. The final, actual cost may be more or less, depending on how much B/D ends up actually being used for treatment. "Touch ups", if needed, done at a time subsequent to the original treatment time, will be an additional charge.

Photographs or Video for Before and After Comparison of Botox and/or Dysport Treatment

By signing this consent document, you expressly allow Dr McGuiness or his representative to use your still pictures or video documenting your before and after appearance, associated with B/D treatment. Your identity will be kept confidential, and not used in association with any likeness of you on the website, or any marketing materials.

Disclaimer

I acknowledge that I understand English and that I have read the preceding information on treatment with Botox and/or Dysport. I was given sufficient opportunities to read this consent document, and to discuss it and ask any questions I had about it with my healthcare provider. I understand fully the content of this document, and have had all my questions answered to my satisfaction, about my condition, the proposed treatment(s), and I agree that I have sufficient knowledge to make a proper informed decision about whether to have treatment with B/D or not.

I am aware and acknowledge that no guarantee or promise has been made to me about the results of treatment with B/D, and that the risks and complications of treatment with B/D, some of which are in this document, can and do sometimes occur. I understand and accept the potential for these risks associated with treatment with B/D.

body area(s) to be treated	product used	# of units to be used	date
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proposed cost	patient signature	injector signature	witness signature
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CONSENT FOR BOTOX OR DYSPORT (B/D) INJECTION (continued)

I acknowledge, by signing below, that I have read the five page consent document for Botox and Dysport treatment provided by the office of Dr Michael McGuiness, have had all my questions about such treatment answered to my satisfaction, and fully understand the risks and benefits of said treatment. Further, it is my desire to proceed with treatment with B/D at this time.

body area(s) to be treated	product used	# of units to be used	date
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proposed cost	patient signature	injector signature	witness signature
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