Informed Consent

Botulinum Toxins—Botox®, Dysport®, Xeomin®, Jeaveau® Neurotoxins

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INSTRUCTIONS

This is an informed consent document to help you learn about Botulinum toxin A (BTA) injections like BOTOX®, Dysport®, Xeomin®, and Jeauveau®. It will outline the risks and other treatments.

It is important that you read the whole document carefully. Please initial each page. Doing so means you have read the page. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

Clostridium botulinum is a type of bacteria that produces a type of chemical compound known as "toxins." One of these, Botulinum toxin A (BTA), is processed and purified to produce a sterile product that has many medical uses. The diluted toxin can be injected into the body. This causes temporary muscle weakness (called chemodenervation) because it stops nerves from sending signals to your muscles. This muscle weakness can last about three to four months.

BOTOX® has been approved to treat certain conditions like crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder in the neck), and issues involving nerves in the face. In April 2002, the FDA also approved BOTOX® to treat wrinkles between the eyebrows caused by specific muscle groups. It's also possible to treat other conditions in other areas, like crow's feet wrinkles and neck bands. These treatments are called "off-label" uses. BOTOX® has also been used to treat migraine headaches, colorectal disorders, heavy armpit and hand sweat, and musculoskeletal pain disorders.

BTA injections are different for each patient. Treatment depends on each patients' needs. You can be treated in many areas, including your eyelids, forehead, and neck. BTA cannot stop you from aging. However, it can temporarily make wrinkles look smoother. BTA injections may be done on their own or combined with other treatments, including surgeries.

OTHER TREATMENTS

There are other ways to deal with skin wrinkles, like skin excision (that is, eyelid surgery or brow lift), chemical peels, and injectable fillers. You can also go in for nonsurgical skin tightening using energy devices like lasers. All treatments have their own risks and possible problems. You can also decide not to have any treatment at all.

SPECIFIC RISKS OF BOTOX® (BOTULINUM TYPE A TOXIN) INJECTIONS

Incomplete Result:

It's possible that you won't be satisfied with the result, or that your results may not be complete. You can go in for more injections to get the results you want. However, sometimes, the results may continue to not meet your goals.

Asymmetry:

It's normal for your face and eyelids to be a little different from side to side. There may also be differences in how parts of your face respond to BTA injections.

Paralysis of Other Muscles:

Although the person who gives you the injection will do his or her best to weaken only the muscles you want smoother, it's possible that the BTA will move and weaken other muscles. You might notice some muscle weakness in other places. This might include drooping eyelids, trouble swallowing, and trouble smiling

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normally. If you have problems like this, your doctor might suggest other treatments. This can include other medications or more BTA injections to make your appearance more even.

Eye Issues:
Some people have trouble closing their eyes after BTA injections. You may also have problems in your cornea due to dryness. This is rare but if it happens, you may need more treatments such as protective eye drops, contact lenses, or surgery. It's not common, but some people have double vision if the BTA weakens the muscles that control their eyes. In some very rare cases, you may go blind after BTA injections.

Eyelid Ectropion:
Your lower eyelids may become very loose or droopy after BTA treatment.

Antibodies to BTA:
Your body may form antibodies to BTA. Future BTA injections may not work as well. We do not know if these antibodies can have other effects on your health.

Neuromuscular Disorders:
You may have peripheral motor neuropathic disorders (pain, weakness, or numbness in your hands and feet). You may also have disorders like amyotrophic lateral sclerosis, myasthenia gravis, and motor neuropathies that affect your nerve cells. If this happens, you may be at a higher risk of problems or side effects from using BTA.

Migraine Headaches:
BTA can be used in the forehead to treat migraine headaches. The results of treatments like this can vary from person to person. Your migraines may or may not get better after using BTA.

Long-Term Effects:
Your appearance naturally changes over time. How your face and eyelids look can change for many reasons, including aging, weight loss or gain, sun exposure, pregnancy, and menopause. These have nothing to do with BTA injections. Using BTA does not stop you from aging. It does not permanently tighten or smooth your skin. You may need other treatments or surgery to help look the way you want.

Pregnancy and Nursing Mothers:
There are no animal studies that demonstrate if using BTA can harm a developing baby. We do not know if BTA can be found in human milk. Pregnant women and nursing mothers shouldn't get BTA treatments. Please tell your doctor if you are or could be pregnant, or if you are nursing.

Unknown Risks:
We don't know the long-term effects of BTA. We don't know all the risks and outcomes of injecting BTA and we can't predict all the results. New risks may be discovered later.

Off-Label Use:
The US Food and Drug Administration (FDA) has approved certain uses of BTA. There are other uses that are common and effective but not specifically approved by the FDA. These are called "off-label" uses. The person giving you treatment may choose to use BTA in these ways based on his or her assessment of the benefits and risks to you.

Drug Interactions:
How BTA affects you can change if you're taking certain drugs. These include antibiotics or other drugs that change how your muscles and nerves communicate.

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DISCLAIMER

Informed consent documents give you information about a surgery you are considering. These documents explain the risks of that surgery. They also discuss other treatment options, including not having surgery. This document is made after a full review of scientific literature and clinical practices. They describe a range of common risks and other forms of management of a disease.
However, informed consent documents can't cover everything. Your plastic surgeon may give you more or different information. This may be based on the facts of your case.

Informed consent documents are not meant to define or serve as the standard of medical care. Standards of medical care are determined based on the facts involved in an individual case. They may change with advances in science and technology. They can also change with the way doctors practice medicine.

It is important that you read the above information carefully and get all your questions answered before signing the consent agreement on the next page.

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CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Thomas Jeneby and the doctor's assistants to give me **Botulinum Toxins—Botox®, Dysport®, Xeomin®, Jeaveau® Neurotoxins.**
2. I got the information sheet on Botulinum Toxins—Botox®, Dysport®, Xeomin®, Jeaveau® Neurotoxins.
3. I understand that, during the treatment, an unexpected situation may require a different medical procedure than the surgery listed above. I permit the doctor listed above, the assistants, and/or designees to provide any treatment(s) that my doctor thinks are needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the surgery.
4. I understand what my doctor can and cannot do. I understand that no warranties or guarantees have been hinted at or stated outright about the outcome of the surgery. I have explained my goals. I understand which outcomes are realistic and which are not. All my questions have been answered. I understand the procedure's risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the procedure.
5. I agree to the anesthetics and medications that are needed or helpful. I understand that all types of anesthesia have risks and may result in complications, injury, and even death.
6. I am aware of the serious risks to my health when blood products are used. I agree to my doctor using them if my doctor, assistants, and/or designees think they are needed or helpful.
7. I agree to the disposal of any tissue, medical devices, or body parts taken out during or after surgery. I also agree to any additional surgeries or treatments that are needed or helpful.
8. I agree to have parts of my body photographed or televised appropriately before, during, and after the surgery for medical, scientific, or educational reasons, if the pictures do not reveal my identity.
9. For medical education, I agree that onlookers can be in the operating room.
10. I permit my Social Security Number to be given to the right agencies for legal reasons and medical device registration, when necessary.
11. I agree to the charges for this procedure. I understand that the doctor's charges are separate from the charges for the hospital and the anesthesia. I understand that there may be more charges if more procedures or treatments are needed or helpful. I agree to those charges, if any.
12. I understand that not having the procedure is an option and that I can opt out of having the procedure.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE PROCEDURE TO BE PERFORMED
    b. THERE MAY BE OTHER SURGERIES OR TREATMENT OPTIONS
    c. THERE ARE RISKS TO THE PROCEDURE

I CONSENT TO THE PROCEDURE AND THE ITEMS THAT ARE LISTED ABOVE (1-13).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____
Patient or Person Authorized to Sign for Patient Date/Time

_____
Witness Date/Time

_____ Patient Initials

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