

BOTOX (Botulinum A Toxin) INFORMED CONSENT

I, _____, understand that I will be injected with Botulinum A Toxin (Botox) in areas around my head (including near my eyes) to paralyze these muscles temporarily.

Botulinum A Toxin (Botox) injection has been Food and Drug Administration (FDA) approved for use in the cosmetic treatment for glabellar frown lines (the wrinkles between the eyebrows), and for areas around the head to treat migraine headaches. Other areas where Botox may be injected, and which is not FDA approved, may be considered an “off-label” use which may increase the risk of side effects.

Injection of Botox into the small muscles between the brows causes those specific muscles to halt their function (be paralyzed), thereby improving the appearance of the wrinkles. Similarly, Botox injection into the larger muscles around the head may causes those specific muscles to halt their function (be paralyzed), thereby decreasing muscular tension which contributes to headaches. This paralysis is temporary, and re-injection is necessary within three to four months. It has been explained to me that other temporary and more permanent treatments are available.

The possible side effects of Botox include but are not limited to:

- 1. Risks: I understand there is a risk of swelling, rash, headache, local numbness, pain at the injection site, bruising, respiratory problems, and allergic reaction.**
- 2. Infection:** Infections can occur which in most cases are easily treatable but in rare cases a permanent scarring in the area can occur.
3. Most people have lightly swollen pinkish bumps where the injections went in, for a couple of hours or even several days.
4. Although many people with chronic headaches or migraines often get relief from Botox, 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.
5. Local numbness, rash, pain at the injection site, flu like symptoms with mild fever, back pain.
6. Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.
7. Bruising is possible anytime you inject a needle into the skin. This bruising can last for several hours, days, weeks, months and in rare cases the effect of bruising

could be permanent.

8. While local weakness of the injected muscles is representative of the expected pharmacological action of Botox, weakness of adjacent muscles may occur as a result of the spread of the toxin.
9. **Treatments:** I understand more than one injection may be needed to achieve a satisfactory result.
10. Another risk when injecting Botox 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. This reduced blinking has been associated with corneal ulcerations. 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.
11. I will follow all aftercare instructions as it is crucial I do so for healing.

As Botox 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 Botox as there are both known and unknown side effects associated with any medication or procedure.

Botox should not be administered to a pregnant or nursing woman.

WARNINGS AND PRECAUTIONS

Pre-Existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of BOTOX®

ADVERSE REACTIONS

Chronic Migraine

The most frequently reported adverse reactions following injection of BOTOX® for chronic migraine include neck pain (9%), headache (5%), eyelid ptosis (4%), migraine (4%), muscular weakness (4%), musculoskeletal stiffness (4%), bronchitis (3%), injection-site pain (3%), musculoskeletal pain (3%), myalgia (3%), facial paresis (2%), hypertension (2%), and muscle spasms (2%).

Post Marketing Experience

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

Additionally:

The number of units injected is an estimate of the amount of Botox 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 Botox treatments with the above understood. I hereby release the doctor, the person injecting the Botox and the facility from liability associated with this procedure.

Patient Signature _____ *Date:* _____