

BOTOX®

Note: Botox is FDA approved for treatment of Blepharospasm and Cervical Dystonia. It has been used extensively for the treatment of overactive facial musculature resulting in wrinkling but is NOT FDA approved for this condition. The most common areas of use are:

- 1. Frown Lines** (In between the eyes)
- 2. Forehead Wrinkles**
- 3. Crow's Feet** (Smile lines around the eyes)

BOTOX® is a therapeutic muscle-relaxing agent that works at motor nerve endings (nerves that lead to muscles). It is in a class of drugs called neurotoxins. When considering neurotoxin therapy, it is important to understand how the product works, the history of its use in patients, its protein content, and possible side effects. This page is designed to help you understand more about BOTOX®: what it is, how it works, and how it can help you.

What is BoTox?®

BOTOX® is a novel therapeutic agent derived from the bacterium, Clostridium Botulinum. Also known as Botulinum Toxin Type A, the brand BOTOX® is produced in controlled laboratory conditions and given in extremely small therapeutic doses.

Botulinum Toxin Type A is the most studied of the seven different serotypes of botulinum toxin (A, B, C1, D, E, F, G). Each serotype has different properties and actions. No two are exactly alike.

How Does BOTOX® Work?

Normally your brain sends electrical messages to your muscles so that they can contract and move. The electrical message is transmitted to the muscle by a substance called acetylcholine. BOTOX® works to block the release of acetylcholine and, as a result, the muscle doesn't receive the message to contract. This means that the muscle spasms stop or are greatly reduced after using BOTOX®, providing reliable relief from symptoms.

How is BOTOX® Administered?

BOTOX® is injected into the muscle. Your doctor will determine the muscle(s) in need of treatment.

Does the Treatment Hurt?

A very fine needle is used for the injection. Some patients report minor and temporary discomfort from the injection.

When does BOTOX® begin to work?

The initial effect of the injection is seen within three days and reaches a peak at one to two weeks post-treatment.

How Long Does the effect Last?

Given its unique mechanism of action, BOTOX® offers sustained relief, dose after dose over the course of long-term treatment. The relief you will feel from a single treatment of BOTOX® will normally be sustained for approximately three to four possibly six months. You will notice a gradual fading of its effects. At this point you will return to your doctor for your next treatment.

Usually, BOTOX® treatment is required only two or three times a year. Symptoms may vary throughout the course of the condition, and so the degree of relief and duration of effect varies from person to person.

How Long can I be treated with BOTOX®?

Treatment with BOTOX® can typically be repeated as long as the patient continues to respond and does not have a serious allergic reaction. BOTOX® has been used for over 10 years commercially worldwide. Acceptable safety in long-term treatment has been well established. However, formal clinical evaluations of long-term treatment have not been conducted.

There are a number of factors that can impact the long-term usage of BOTOX®. These include:

1. **Setting appropriate expectations** - Changes occurring with subsequent BOTOX® injections may be less dramatic than the first injection.
2. **Appropriate muscle selection** - Identifying and injecting the affected muscle can be difficult, complicated by the changing pattern of muscle involvement and progression of the disorder.
3. **Adequate dosing** - Changes in response may require dose adjustment.

4. **Minimizing exposure to neurotoxin complex proteins¹** - Botulinum toxins contain proteins. In certain circumstances, when foreign proteins enter the body, the natural response is to form antibodies to the protein. When antibodies are formed, the effect may be that one is no longer able to respond to the therapy. High doses and frequent injections of botulinum toxin have been linked to the formation of antibodies.^{2,3} Formation of neutralizing antibodies to botulinum toxin type A may reduce the effectiveness of BOTOX®. The rate of formation of neutralizing antibodies in patients receiving BOTOX® has not been well studied. The likelihood of forming antibodies may be reduced by maximizing the interval between treatments. BOTOX® has approximately 5 ng of neurotoxin complex proteins per 100 unit vial. The critical factors for neutralizing antibody formation have not been well characterized. The results from some studies suggest that BOTOX® injections at more frequent intervals or at higher doses may lead to greater incidence of antibody formation. The potential for antibody formation may be minimized by injecting with the lowest effective dose given at the longest feasible intervals between injections. Well-controlled studies designed to determine the rate of formation of neutralizing antibodies in patients receiving BOTOX® have yet to be conducted.

Is BOTOX® a New Treatment?

No. BOTOX® has been used commercially for over 10 years in thousands of patients worldwide.

What Side Effects Can I expect?

All medications have some side effects. With BOTOX®, side effects are usually transient and mild to moderate in nature. Some people notice temporary weakness of muscles or discomfort at the injection site.

At times BOTOX® can migrate into areas that were not intended to be treated including the eye muscles causing double vision due to eye muscle incoordination or excessive brow droopiness.

Please Ask Dr. Griffiths if you have any other questions regarding BOTOX®.