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Botox® Cosmetic Therapy Consent Form

Overview

Therapy with Botox® Cosmetic (botulinum toxin Type A) is a nonsurgical treatment that can temporarily smooth moderate to severe facial expression wrinkles by utilizing several small injections. Botox® Cosmetic is a purified protein produced by the *Clostridium botulinum type A* bacterium, which temporarily reduces activity of muscles which have caused those wrinkles to form over time. Botox® Cosmetic is approved by the United States Food and Drug Administration (FDA) for the treatment of frown lines between the eyebrows (glabellar lines) for those aged 18 to 65, although it is widely used off-label to improve the appearance of forehead wrinkles, crow's feet wrinkles, and the lower face, amongst other areas.

Procedure

Injection of a small amount of Botox® Cosmetic into specific muscles causes weakness at those muscles and gradual improvement of the overlying hyperkinetic wrinkles (wrinkles in motion).

When Botox® Cosmetic is reconstituted from its vacuum-dried preparation, it is sterilely diluted into a controlled solution prior to injection. The injections of the product are performed at targeted areas using a small, thin needle causing a minimal amount of discomfort, although a slight burning sensation during the injection is not uncommon.

Anticipated Benefits/Duration of Action

A response to the treatment is usually noted between 2 and 10 days following injection. Optimal results may not be seen until 2 weeks, and may, in fact, take longer to achieve. The results of the muscle relaxation are effective on average between 3 and 5 months, although individual results may vary, and variability can be present depending upon a variety of factors including depth of the lines, size of the muscles, quantity of product utilized, and frequency of re-treatment. Subsequent treatment series may potentially increase the duration of action of therapy. Additional "touch-up" treatments may be required to improve the effects of any given injection series.

Some patients may be less sensitive to the effects of Botox® Cosmetic for unknown reasons. Some patients may develop antibodies to Botox® Cosmetic which may render them more resistant to treatment.

Outcomes

Occasionally, despite proper planning, patients do not always respond as desired to Botox® Cosmetic therapy.

Risks and Complications

Side effects, in addition to mild swelling and redness, localized infection, respiratory infection, nausea, and flu-like symptoms may include:

- Pain at injection site: Usually mild and transient; often relieved with Tylenol.
- Bruising: Usually at or near the injection site; may be increased by the recent use of products such as aspirin, ibuprofen, naproxen, warfarin, and vitamin E; may be present for 7 to 10 days post-treatment.
- Bumps: Localized, slightly swollen and raised areas may be present at the

- injection sites, which may be present for several hours to several days.
- Headache: Usually mild and transient; commonly lasts for less than 24 hours; may be relieved with Tylenol.
- Asymmetry: Usually presents within initial 2 weeks of treatment; often may be corrected with additional "touch-up" injections as needed.
- eyebrow or eyelid ptosis (droop) and double vision (diplopia): Seen in 1-2% of patients receiving Botox® Cosmetic therapy; usually lasts for 2 to 4 weeks; resolution may be expedited with prescription eye drops.
- Adjacent muscle weakening: Rarely, a muscle adjacent to the targeted muscle may be weakened for several days post-treatment.
- Muscle twitching: May be corrected with additional "touch-up" injections.
- Numbness: May be described as a "dullness"; if present, usually lasts no more than several days post-treatment; no additional therapy needed.

Contraindications

Absolute and/or relative contraindications to Botox® Cosmetic treatment include patients with a prior allergic reaction; an allergy to eggs; fever, flu, or cold symptoms; infection at the proposed injection site(s); pregnant or breastfeeding women; neurologic diseases (such as ALS, myasthenia gravis, Lambert-Eaton syndrome, multiple sclerosis); marked pre-treatment asymmetry; and consumption of alcohol within 48 hours of treatment.

Patients taking aminoglycoside antibiotics, penicillamine, quinine, and calcium channel blockers may have a magnification of the effects of treatment and side effects.

Alternatives

Alternatives to wrinkle-reduction therapy include prescribed creams, chemical peels, laser resurfacing, surgical treatments such as removal of muscle or forehead and eyebrow lift, and dermal filler injections.

Post-Treatment Instructions

- No lying down or bending forward for at least 4 hours post-treatment.
- No manipulation of treated location(s) for at least 4 hours post-treatment.
- Avoid touching the treated area(s) within 6 hours following treatment.
- Avoid strenuous exercise activity for the remainder of the day of treatment.
- Avoid alcohol consumption for the remainder of the day of treatment.
- Avoid hot baths or hot tubs for the remainder of the day of treatment.
- Actively moving the targeted muscles every 15 minutes during the first hour post-treatment may assist in increasing and expediting the response of the targeted muscles to the Botox® Cosmetic therapy.
- Avoid exposure of the treated area(s) to intense heat, such as during sunbathing or tanning lamps, until any redness or swelling has dissipated.

Fees

Our practice charges Botox® Cosmetic therapies on a per unit basis. Additional fees apply for future "touch-up" therapies.

Follow-up Visit

We request that patients follow up in 2 to 3 weeks post-treatment for re-evaluation. Touch-up therapies may be necessary at these subsequent visits.

Consent

I have read this Botox® Cosmetic Therapy Consent Form and understand it in its entirety. I have had the opportunity to ask questions to my treating provider which have been answered to my satisfaction. I voluntarily consent to Botox® Cosmetic treatment, and I accept the risks and possible complications of this procedure. I am aware that no guarantees have been made regarding the results of this procedure. I understand that photographs may be taken before and/or following treatment and will be kept confidential and will become part of my medical record.

Patient Signature/Date

Physician Signature/Date

Witness Signature/Date

Patient Name (print)

Physician Name (print)

Witness Name (print)