Consent Form for Dysport Treatment

This is a consent form for Dysport treatment. Please read it carefully before signing.

This disclosure is not meant to alarm you; it is simply an effort to better inform you. Being informed will help you make the decision whether to undergo treatment.

What is Dysport? Dysport is the trademark for abobotulinumtoxin-A. It is a prescription medication, acetylcholine release inhibitor, and neuromuscular blocking agent that is injected into muscles.

Indications for Treatment: Dysport is approved by the FDA (Food and Drug Administration) for the following indications:

- The temporary improvement in the appearance of moderate to severe glabellar lines
- The treatment of cervical dystonia in adults
- The treatment of spasticity in patients 2 years of age and older

These are the "on-label" uses for Dysport. These types of injections have also been used for more than a decade to improve spasms of the muscles around the eye, to correct double vision due to muscle imbalance as well as numerous other neurological uses.

Injections into other areas to improve the appearance of facial lines have been commonly used and reported in the medical literature, but these are "off label" uses and not approved by the FDA. Dysport is also used "off-label" to improve eyebrow position, gummy smile, downturned corners of mouth, chin dimpling, perioral lines, jaw width, bruxism, jawline definition and lower face contour, neck bands, horizontal neck lines, scars, and skin rejuvenation.

Alternatives to treatment: There are alternatives to Dysport treatment including no treatment at all, or treatment using other neuromodulators like Botox, Xeomin, Jeuveau, and Daxxify, facial soft tissue augmentation or implants, hyaluronic acid fillers like Restylane and Juvederm, laser skin resurfacing, chemical peels, cosmeceuticals, or plastic surgery for wrinkle reduction.

Results: The actual degree of improvement cannot be predicted or guaranteed. Furthermore, the effect will gradually wear off and additional treatments will be necessary to maintain the desired effect. Static permanent lines at rest, so called "etched" lines, will not be erased with Dysport alone. New lines may form or be more visible. Eyebrow position may change. Using concentrated and higher doses may result in more dramatic and longer lasting improvement. The patient is responsible for the cost of each Dysport unit and treatment without guarantee of results.

Side effects and complications: Common side effects are headache, injection site pain, bruising, upper respiratory tract infection, sinusitis, eyelid ptosis, swelling of eyelids, dry eyes, double vision, and nausea.

The effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported

hours to weeks after injection. These risks are probably greatest in children treated for spasticity, but symptoms can occur in adults, particularly those patients who have underlying conditions that would predispose them to these symptoms.

More serious complications include difficulty swallowing, difficulty breathing, and allergic reaction or anaphylaxis.

Precautions and contraindications: Dysport should not be used if there is an infection at the injection site.

The safety of Dysport in pregnant and breastfeeding women has not been established and is therefore not recommended in these women.

Patients with an allergy to any of the components of Dysport which includes human albumin, lactose and cow's milk protein should not have this treatment. Dysport is commonly reconstituted using preserved saline which contains benzoyl alcohol and if you have an allergy to benzoyl alcohol, please let Dr. Patel know as non-preserved saline may be used instead.

Patients with swallowing or breathing difficulties and muscle or nerve conditions such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis, or Lambert-Eaton syndrome should not have this treatment as it may increase the risk of serious side effects including difficulty swallowing and difficulty breathing.

Dysport contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Local anesthesia may be used to reduce discomfort of the procedure including the topical application of anesthetic cream or ointment.

By signing below, you consent that you have read the above consent, understand it, and have had the risks, benefits, and alternatives explained to you, and have had the opportunity to ask questions and refuse treatment. You have chosen this treatment voluntarily and no guarantees about results have been made. Further treatments may be needed. To the best of your knowledge, you are not pregnant or breastfeeding and do not have an allergy to Dysport or any its components. You give informed consent for Dysport treatment today as well as future treatments as needed by Dr. Shaun Patel. Further information is available upon request.

Patient signature _____

Date: _____

Witness signature _____

Date: _____