



### Consent For BOTOX® Cosmetic and DYSPORT® (onabotulinumtoxinA)

\_\_\_\_\_ I understand that all skin reacts to treatments in some manner, and agree that I will notify the Manager as soon as possible if I experience a reaction that does not resolve within several hours or becomes progressively worse after leaving. I agree to follow all care instructions given by Setty Plastics and Aesthetics and understand that I will achieve optimal healing by following all home care instructions.

\_\_\_\_\_ I understand Indications Glabellar Lines BOTOX® Cosmetic and DYSPORT® (onabotulinumtoxinA) for injection is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients. Lateral Canthal Lines BOTOX® Cosmetic and DYSPORT® are indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients. ã

\_\_\_\_\_ I understand postmarketing reports indicate that the effects of BOTOX® Cosmetic, DYSPORT® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and upper limb spasticity and at lower doses.

\_\_\_\_\_ I understand BOTOX® Cosmetic and DYSPORT® are contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation. I understand no definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic and DYSPORT® at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

\_\_\_\_\_ I understand serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® and DYSPORT® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® and DYSPORT® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX® and DYSPORT®. The safety and effectiveness of BOTOX® and DYSPORT® for unapproved uses have not been established.

\_\_\_\_\_ Hypersensitivity Reactions, serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic and DYSPORT® should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

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\_\_\_\_\_ I understand there have been reports following administration of BOTOX® and DYSPORT® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease.

\_\_\_\_\_ I understand individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see Warnings and Precautions).

\_\_\_\_\_ I understand Dysphagia and Breathing Difficulties Treatment with BOTOX® and DYSPORT® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see Boxed Warning).

\_\_\_\_\_ I understand Pre-existing Conditions at the Injection Site Caution should be used when BOTOX® Cosmetic and DYSPORT® treatments are used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

\_\_\_\_\_ I understand this product 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. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

\_\_\_\_\_ I understand the most frequently reported adverse event following injection of BOTOX® Cosmetic for glabellar lines was eyelid ptosis (3%). The most frequently reported adverse event following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

\_\_\_\_\_ I understand co-administration of BOTOX® Cosmetic and DYSPORT® and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic and DYSPORT® may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX® Cosmetic and DYSPORT®.

\_\_\_\_\_ I consent to the use of photographs for recordkeeping purposes; these photographs may be taken before, during and after my treatments.

\_\_\_\_\_ I consent to the use of these photographs for providing information to other clients and to the public about my treatment. They may be shown during client consultations, as well as public promotional lectures and demonstrations, and may be reproduced in educational, instructional and promotional literature and on the Setty Plastics and Aesthetics website and social media outlets managed by Setty Plastics and Aesthetics and its employees. My identity will not be compromised.

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\_\_\_\_\_ I confirm I am not currently pregnant or nursing and agree I will inform the technician if I do become pregnant, or am nursing in the future. I understand I cannot receive treatments while pregnant or breastfeeding. There are no known side effects, however, these treatments cannot be tested on pregnant or nursing women.

\_\_\_\_\_ I understand I have the option of a 2 week follow up appointment, which is encouraged by Setty Plastics and Aesthetics to ensure safety and desired results have been achieved. I understand that a physician will be available for evaluation and followup issues. Determination for an appointment with a physician will be made in consultation with management and myself.

\_\_\_\_\_ I have read and understand all the information presented to me before signing this consent. I understand the risks of side effects, despite proper treatment, exist in **all** cases, but can be greatly reduced by following the pre and post treatment instructions given to me. I understand the purpose of the procedures. I further understand that treatment results **will** vary between individuals and treated areas. I understand that there are many variables that may affect my treatments and that I have been made no promises of any results.

## **BOTOX, DYSPORT AND DERMAL FILLER PRE & POST-TREATMENT INSTRUCTIONS**

### Pre-Treatment

- Do NOT consume alcoholic beverages at least 24 hours prior to treatment (alcohol may thin the blood and increase the risk of bruising), avoid anti-inflammatory/blood thinning medications, if possible for a period of 2 weeks before treatment, or any blood thinning medications which can increase the risk of bruising and swelling after injections.
- Schedule your appointment at least 2 weeks prior to a special event. Results from the injections may take approximately 4 to 7 days to appear. Also bruising and swelling may be apparent in that time period.
- Discontinue Retin-A 2 days before and 2 days after treatment.
- Reschedule your appointment at least 24 hours in advance if you have a rash, cold sore or blemish on the area. Notify Setty P if you have a history of cold sores.
- Be sure to have a good breakfast, including food and drink before your procedure. This will decrease the chances of lightheadedness during your treatment.
- You are not a candidate if you are pregnant or breast feeding.

### Post-Treatment

- Do NOT manipulate the treated area for 3 hours following treatment. Do NOT receive facial/ laser treatments or microdermabrasion after Botox or Dysport injections for at least 10 days. Ask your provider if you are not sure about the time frame of certain services.
- Some providers believe that smiling and frowning right after Botox or Dysport treatments helps the Botox or Dysport find its way to the muscle into which it was injected after treated.
- Do NOT lie down for 4 hours after your Botox or Dysport treatment. This will prevent the Botox or Dysport from tracking into the orbit of your eye and causing drooping eyelid.

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- It can take approximately 4 to 7 days for results to be seen. If the desired result is not seen after 2 weeks of your treatment you may need additional Botox or Dysport. You are charged for the amount of product used. Therefore, you will be charged for product used during any touch up or subsequent appointments
- Do NOT perform activities involving straining, heavy lifting, or vigorous exercise for 6 hours after treatment. This will keep the Botox or Dysport in the injected area and not elsewhere