Botulinum Toxin Type A: Botox® Cosmetic & Dysport Consent Form

Botox® Cosmetic

Botox® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe glabellar and lateral canthal lines associated with corrugator and/or procerus muscle activity in adult patients < 65 years of age.

Botox® Cosmetic for injection, is sterile, vacuum-dried purified protein botulinum toxin type A, produced from fermentation of Hall strain Clostridium botulinum type A grown in a medium containing casein hydrolysate, glucose, and yeast extract, intended for the intramuscular use. Botox® Cosmetic blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine. This inhibition occurs as the neurotoxin cleaves SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. When injected intramuscularly at therapeutic doses, Botox® Cosmetic procedures partial chemical denervation of the muscle resulting in a localized reduction in muscle activity.

Administration of Botox® Cosmetic is not recommended during pregnancy. There are no adequate and well controlled studies of Botox® Cosmetic in pregnant women. It is not known whether this rug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised with Botox® Cosmetic is administered in nursing women.

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Dysport ™

Dysport ™ is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age.

The effects of Dysport ™ and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effect. 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, particular in those patients who have underlying conditions that would predispose them to these symptoms.

Dysport ™ is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation. This product may contain trace amounts of cow's milk protein. Patients know to be allergic to cow's milk protein should not be treated with Dysport ™. Dysport ™ is contraindicated for use in patients with infection the proposed injection site(s).

There are no adequate and well-controlled studies in pregnant women. Dysport ™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known where Dysport ™ is excreted in human milk.

I authorize and direct Prescott Medical Aesthetics to perform the following procedure of Botox® Cosmetic and/or Dysport ™ injections on _____ (patient name) for the treatment of (areas to be treated:

□ Glabella Initials: _____

□ Forehead Initials: _____

□ Crows Feet Initials: _____

□ Other Initials: _____

Please initial the following:

_____ The details of this procedure have been explained to me in terms I understand.

_____ Alternative methods and their benefits and disadvantages have been explained to me.

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_____ I understand that the FDA has only approved the cosmetic use of Botox® Cosmetic and Dysport™ for frown lines and crow's feet. Any other cosmetic use is considered off-label.

_____ I understand and accept that most likely risk complications of Botox® Cosmetic and Dysport™ injections, including but not limited to:

- Paralysis of a nearby muscle that could interfere with opening of the eye(s)
- Local numbness
- Headache, nausea, or flu-like symptoms
- Swallowing, speech, or respiratory disorders
- Swelling, bruising or redness at the injection site
- Disorientation and double vision
- Temporary asymmetrical appearance
- Abnormal or lack of facial expression
- Inability to smile when injected in the lower face
- Facial Pain
- Product ineffectiveness

_____ I understand and accept that the long-term effects of repeated use of Botox® Cosmetic and Dysport™ injections are unknown. Possible risk and complication that have been identified, but are not limited to:

- Muscle atrophy
- Nerve irritability
- Production of antibodies with unknown effect to general health

_____ I understand and accept the less common complications, including the remote risk of death or serious disability that exists with this procedure.

_____ I am aware that smoking during the pre and post operative periods could increase chances of complications ind increase healing time.

_____ I have informed the doctor or nurse of all my known allergies, including allergies to latex.

_____ I have informed the doctor or nurse of all medications I am currently taking including prescriptions, over the counter medications/remedies, herbal therapies and any other treatments I am currently doing.

_____ I am aware and accept that no guarantees regarding the result of this procedure have been made or implied. I am aware that this procedure is completely voluntary, and treatment is not necessary. Alternative treatments include but are not limited to: doing nothing, cosmetic surgery, laser treatments, chemical peels, and Botox.

_____ Prices are subject to change. The pricing I receive during this treatment is only for today's treatment. Any additional treatments, products or services will be billed at rates effective at time of the additional treatments.

_____ I am not currently pregnant or nursing.

_____ I have been advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

_____ I certify that I have read and understand this agreement and that all spaces for initials were filled prior to my signature.

PRINT NAME: _____ **DATE:** _____

PATIENT SIGNATURE: _____ **DATE:** _____

I certify that I have explained the nature, purpose, benefits, risks, complications and alternatives of the proposed procedure to the patient. I have answered fully, and I believe that the patient fully understands what I have explained.

DOCTOR OR NURSE SIGNATURE: _____ **DATE:** _____