



**PATIENT CONSENT TO MEDICAL TREATMENT OR SURGICAL PROCEDURE AND  
ACKNOWLEDGMENT OF RECEIPT OF MEDICAL INFORMATION**

**TO THE PATIENT:** You have been told that you should consider medical treatment/surgery.

- (1) the nature of your condition
- (2) the general nature of the medical treatment/surgery
- (3) the risks of the proposed treatment/surgery, as determined by your doctor
- (4) reasonable therapeutic alternatives and material risks associated with such alternatives
- (5) risks of no treatment.

You have the right, as a patient, to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved.

In keeping with the North Carolina law of informed consent, you are being asked to sign a confirmation that we have discussed all these matters. We have already discussed with you the common problems and risks. We wish to inform you as completely as possible.

Please read the form carefully. Ask about anything you do not understand, and we will be pleased to explain.

1. **Patient name:** \_\_\_\_\_

2. **Treatment/procedure:** \_\_\_\_\_

(a) Description, nature of the treatment/procedure: Botox Cosmetic

- I. A combination of factors can cause facial lines. It's not just about the cellular changes that may occur, or reduction of collagen, or damage caused by free radicals from the sun and the environment.
- II. Repeated muscle contractions from frowning, squinting, or raising eyebrows cause skin to furrow and fold, gradually resulting in the formation of facial lines. BOTOX® Cosmetic works beneath the surface and temporarily reduces the underlying muscle activity that causes moderate to severe frown lines,



crow's feet and forehead lines in adults – to help them look visibly smoother.

(b) Purpose:

**ISSUES ADDRESSED WITH BOTOX® Cosmetic**

BOTOX Cosmetic is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated in adult patients for the temporary improvement in the appearance of (1):

- Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
- Moderate to severe lateral canthal lines associated with orbicularis oculi activity
- Moderate to severe forehead lines associated with frontalis muscle activity

3. Patient Condition: Facial procedure

Patient's diagnosis, description of the nature of the condition or ailment for which the medical treatment, surgical procedure or other therapy described in Item 2 is indicated and recommended:

4. Material risks of treatment procedures:

- (a) All medical or surgical treatment involves risks. Listed below are those risks associated with this procedure that we believe a reasonable person in your (the patient's) position would likely consider significant when deciding whether to have or forego the proposed therapy. Please ask your physician if you would like additional information regarding the nature or consequences of these risks, their likelihood of occurrence, or other associated risks that you might consider significant but may not be listed below.
- I. Problem's swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
  - II. Spread of toxin effects. The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or

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loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing.

- III. BOTOX® Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.
- IV. There has not been a confirmed serious case of spread of toxin effect when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, and/or forehead lines.
- V. BOTOX® Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX® Cosmetic. If this happens, do not drive a car, operate machinery, or do other dangerous activities.
- VI. Serious and/or immediate allergic reactions have been reported. They include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.
- VII. Do not receive BOTOX® Cosmetic if you: are allergic to any of the ingredients in BOTOX® Cosmetic (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); have a skin infection at the planned injection site.
- VIII. Tell your doctor about all your muscle or nerve conditions, such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX® Cosmetic.
- IX. Tell your doctor about all your medical conditions, including: plans to have surgery; had surgery on your face; have trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® Cosmetic can harm your unborn baby); are breast-feeding or plan to (it is not known if BOTOX® Cosmetic passes into breast milk).
- X. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® Cosmetic with certain other medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you have received BOTOX® Cosmetic in the past.
- XI. Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as Myobloc®, Dysport®, or Xeomin® in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.



XII. Other side effects of BOTOX® Cosmetic include: dry mouth; discomfort or pain at the injection site; tiredness; headache; neck pain; and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids and eyebrows, swelling of your eyelids and dry eyes.

(b) Risks generally associated with any surgical treatment/procedure, including anesthesia are: death, brain damage, disfiguring scars, quadriplegia (paralysis from neck down), paraplegia (paralysis from waist down), the loss or loss of function of any organ or limb, infection, bleeding, and pain.

#### **ACKNOWLEDGMENT AUTHORIZATION AND CONSENT**

(a) No Guarantees: All information given me and, in particular, all estimates made as to the likelihood of occurrence of risks of this or alternate procedures or as to the prospects of success, are made in the best professional judgment of my physician. The possibility and nature of complications cannot always be accurately anticipated and, therefore, there is and can be no guarantee, either express or implied, as to the success or other results of the medical treatment or surgical procedure.

(b) Additional Information: Nothing has been said to me, no information has been given to me, and I have not relied upon any information that is inconsistent with the information set forth in this document.

(c) Particular Concerns: I have had an opportunity to disclose to and discuss with the physician providing such information, those risks or other potential consequences of the medical treatment or surgical procedure that are of particular concern to me.

(d) Questions: I have had an opportunity to ask, and I have asked, any questions I may have about the information in this document and any other questions I have about the proposed treatment or procedure, and all such questions were answered in a satisfactory manner.

(e) Authorized Physician: The physician (or physician group) authorized to administer or perform the medical treatment, surgical procedures or other therapy described in item 2 is: **CIRCADIAN REJUVENATION**

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(f) Physician Certification: I hereby certify that I have provided and explained the information set forth herein, including any attachment, and answered all questions of the patient, or the patient's representative, concerning the medical treatment or surgical procedure, to the best of my knowledge and ability.



Signature of Physician (physician group): \_\_\_\_\_ Date/Time: \_\_\_\_\_

**CONSENT**

Consent: I hereby authorize and direct the designated authorized physician/group, together with associates and assistants of his choice, to administer or perform the medical treatment or surgical procedure described in item 2 of this Consent Form, including any additional procedures or services as they may deem necessary or reasonable, including the administration of any general or regional anesthetic agent, x-ray or other radiological services, laboratory services, and the disposal of any tissue removed during a diagnostic or surgical procedure, and I hereby consent thereto.

I have read and understand all information set forth in this document, including any attachment, and all blanks were filled in prior to my signing. This authorization for and consent to medical treatment or surgical procedure is and shall remain valid until revoked.

I acknowledge that I have had the opportunity to ask any questions about the contemplated medical procedure or surgical procedure described in item 2 of this consent form, including risks and alternatives, and acknowledge that my questions have been answered to my satisfaction.

Witness: \_\_\_\_\_

Date/Time \_\_\_\_\_

Patient or Person authorized to consent: \_\_\_\_\_

Date/Time \_\_\_\_\_

If consent is signed by someone other than the patient, state the reason and relationship:

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