I, ______________________________________________________, understand that I will be injected with Botulinum A Toxin (Botox®/Dysport®/ Xeomin®) in the area of the glabellar muscles to paralyze these muscles temporarily or in the forehead or crow's feet around the lateral area of the eyes.

Botulinum A Toxin (Botox®/Dysport®/ Xeomin®) injection has been FDA approved for use in the cosmetic treatment for glabellar frown lines only – the wrinkles between the eyebrows.

Injection of Botox®/Dysport®/Xeomin® into the small muscles between the brows causes those specific muscles to halt their function (be paralyzed), thereby improving the appearance of the wrinkles. I understand the goal is to decrease the wrinkles in the treated area. This paralysis is temporary, and re-injection is necessary within three to four months. It has been explained to me that other temporary and more permanent treatments are available.

The possible side effects of Botox®/Dysport®/Xeomin® include but are not limited to:

**Risks:** I understand there is a risk of swelling, rash, headache, local numbness, pain at the injection site, bruising, respiratory problems, and allergic reaction.

**Infection:** Infections can occur which in most cases are easily treatable but in rare cases a permanent scarring in the area can occur.

Most people have lightly swollen pinkish bumps where the injections went in, for a couple of hours or even several days.

Although many people with chronic headaches or migraines often get relief from Botox®/Dysport®/Xeomin®, a small percent of patients get headaches following treatment with Botox®/Dysport®/Xeomin®, for the first day. In a very small percentage of patients these headaches can persist for several days or weeks.

Local numbness, rash, pain at the injection site, flu like symptoms with mild fever, back pain.

Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.

Bruising is possible anytime you inject a needle into the skin. This bruising can last for several hours, days, weeks, months and in rare cases the effect of bruising could be permanent.

While local weakness of the injected muscles is representative of the expected pharmacological action of Botox®/Dysport®/ Xeomin®, weakness of adjacent muscles may occur as a result of the spread of the toxin.
Treatments: I understand more than one injection may be needed to achieve a satisfactory result.

Another risk when injecting Botox®/Dysport®/ Xeomin® around the eyes included corneal exposure because people may not be able to blink the eyelids as often as they should to protect the eye. This inability to protect the eye has been associated with damage to the eye as impaired vision, or double vision, which is usually temporary. This reduced blinking has been associated with corneal ulcerations. There are medications that can help lift the eyelid, however, if the drooping is too great the eye drops are not that effective. These side effects can last for several weeks or longer. This occurs in 2-5 percent of patients.

I will follow all aftercare instructions as it is crucial I do so for healing.

As Botox®/Dysport®/ Xeomin® is not an exact science, there might be an uneven appearance of the face with some muscles more affected by the Botox®/Dysport®/ Xeomin® than others. In most cases this uneven appearance can be corrected by injecting Botox®/Dysport®/ Xeomin® in the same or nearby muscles. However in some cases this uneven appearance can persist for several weeks or months.

This list is not meant to be inclusive of all possible risks associated with Botox®/Dysport®/ Xeomin® as there are both known and unknown side effects associated with any medication or procedure.

Botox should not be administered to a pregnant or nursing woman. Additionally, The number of units injected is an estimate of the amount of Botox®/Dysport®/ Xeomin® required to paralyze the muscles. I understand there is no guarantee of results of any treatment. I understand the regular charge applies to all subsequent treatments.

I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and/or Court cost and reasonable legal fees, should this be required.

By signing below, I acknowledge that I have read the foregoing informed consent and agree to the treatment with its associated risks. I hereby give consent to perform this and all subsequent Botox treatments with the above understood. I hereby release the doctor, the person injecting the Botox®/Dysport®/ Xeomin® and the facility from liability associated with this procedure.

Patient Signature ___________________________ Date: __________________

Witness ___________________________ Date: __________________
Due to the fact that there are now multiple Botulinum Toxin, Type A products on the market, the FDA has required that all Botulinum toxin, Type A products carry a black box warning label to alert the public of possible adverse reactions or side effects of the toxins, as well as proper use of the toxins, and risk factors associated with their use. This is due to the fact that not all Botulinum toxins are created equal, and the public has a right to be made aware of the differences associated with each toxin that is available to you for injection. The 3 Botulinum toxins available in the USA are Botox®, Dysport®, and Xeomin®. This form is the black box warning that is now required to be present on package inserts. It is important to note that all BoNT-A products are required by the FDA to include the black box warning on package inserts.

Please read the following form, which is the black box warning now on all package inserts of Botox®, Dysport®, and Xeomin® and sign the bottom stating we have made you aware of these new requirements by the FDA.

I have received a copy of the MEDICATION GUIDE for BOTOX® Cosmetic for Injection.

Initial if true ______________

Patient Signature: ___________________________ Date: ____________________

Witness: _______________________________________________________________________

Dr. __________________________ Signature: ____________________________
What are BOTOX® and BOTOX® Cosmetic?

BOTOX® is a prescription medicine that is injected into muscles and used:

- to treat increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

BOTOX® is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

BOTOX® Cosmetic® is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary).

It is not known whether BOTOX® is safe or effective in children younger than:

- 18 years of age for treatment of spasticity
- 16 years of age for treatment of cervical dystonia
- 18 years of age for treatment of hyperhidrosis
- 12 years of age for treatment of strabismus or blepharospasm

BOTOX® Cosmetic® is not recommended for use in children younger than 18 years of age.

It is not known whether BOTOX® and BOTOX® Cosmetic® are safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

Who should not take BOTOX or BOTOX Cosmetic?

Do not take BOTOX or BOTOX Cosmetic if you:

- are allergic to any of the ingredients in BOTOX or BOTOX Cosmetic. See the end of this Medication Guide for a list of ingredients in BOTOX and BOTOX Cosmetic.
- had an allergic reaction to any other botulinum toxin product such as Myobloc® or Dysport®
- have a skin infection at the planned injection site

What should I tell my doctor before taking BOTOX or BOTOX Cosmetic?

Tell your doctor about all your medical conditions, including if you have:

- a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS] or Lou Gehrig’s disease), myasthenia gravis or Lambert-Eaton syndrome. See “What is the most important information I should know about BOTOX and BOTOX Cosmetic?”
- allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- a breathing problem, such as asthma or emphysema
- swallowing problems
- bleeding problems

These problems could make it unsafe for you to drive a car or do other dangerous activities. See “What Should I Avoid While Receiving BOTOX or BOTOX Cosmetic?”

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat severe underarm sweating, blepharospasm, or strabismus, or when BOTOX® Cosmetic® has been used at the recommended dose to treat frown lines.

Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:

- loss of strength and muscle weakness all over the body
- double vision
- blurred vision and drooping eyelids
- hoarseness or change or loss of voice (dysphonia)
- trouble saying words clearly (dysarthria)
- loss of bladder control
- trouble breathing
- trouble swallowing

These symptoms can happen hours to weeks after you receive an injection of BOTOX or BOTOX Cosmetic.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See “What Should I Avoid While Receiving BOTOX or BOTOX Cosmetic?”

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat severe underarm sweating, blepharospasm, or strabismus, or when BOTOX® Cosmetic® has been used at the recommended dose to treat frown lines.
• plans to have surgery
• had surgery on your face
• weakness of your forehead muscles, such as trouble raising your eyebrows
• drooping eyelids
• any other change in the way your face normally looks
• are pregnant or plan to become pregnant. It is not known if BOTOX® or BOTOX® Cosmetic can harm your unborn baby.
• are breast-feeding or plan to breastfeed. It is not known if BOTOX or BOTOX Cosmetic passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products. Using BOTOX or 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 or BOTOX Cosmetic in the past.

Especially tell your doctor if you:
• have received any other botulinum toxin product in the last four months
• have received injections of botulinum toxin, such as Myobloc® (rimabotulinumtoxinB) or Dysport® (abobotulinumtoxinA) in the past. Be sure your doctor knows 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

Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take BOTOX or BOTOX Cosmetic?

• BOTOX or BOTOX Cosmetic is an injection that your doctor will give you.
• BOTOX is injected into your affected muscles or skin.
• BOTOX Cosmetic is injected into your affected muscles.
• Your doctor may change your dose of BOTOX or BOTOX Cosmetic, until you and your doctor find the best dose for you.

What should I avoid while taking BOTOX or BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic may cause loss of strength or general muscle weakness, or vision problems within hours to weeks of taking BOTOX or BOTOX Cosmetic. If this happens, do not drive a car, operate machinery, or do other dangerous activities. See “What is the most important information I should know about BOTOX and BOTOX Cosmetic?”

What are the possible side effects of BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic can cause serious side effects. See “What is the most important information I should know about BOTOX and BOTOX Cosmetic?”

Other side effects of BOTOX® and BOTOX® Cosmetic include:

• dry mouth
• discomfort or pain at the injection site
• tiredness
• headache
• neck pain
• eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.
• allergic reactions. Symptoms of an allergic reaction to BOTOX or BOTOX Cosmetic may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BOTOX and BOTOX Cosmetic. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about BOTOX and BOTOX Cosmetic:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about BOTOX and BOTOX Cosmetic. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about BOTOX and BOTOX Cosmetic that is written for healthcare professionals. For more information about BOTOX and BOTOX Cosmetic call Allergan at 1-800-433-8871 or go to www.botox.com.

What are the ingredients in BOTOX and BOTOX Cosmetic?

Active ingredient: botulinum toxin type A

Inactive ingredients: human albumin and sodium chloride

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by: Allergan Pharmaceuticals Ireland a subsidiary of: Allergan, Inc. 2525 Dupont Dr. Irvine, CA 92612 © 2010 Allergan, Inc.

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U.S. Patents 6,974,578; 6,683,049; and 6,896,886

Myobloc® is a registered trademark of Solstice Neurosciences, Inc.

Dysport® is a registered trademark of Ipsen Biopharm Limited Company.

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