THE TREATMENT
Botulinum toxin, Botox®, Dysport®, Xeomin® are neurotoxins produced by the bacterium Clostridium A. Botulinum toxin can relax the muscles on areas of the face and neck which cause wrinkles associated with facial expressions or facial pain. Treatment with botulinum toxin can cause your facial expression lines or wrinkles to be less noticeable or essentially disappear. Areas most frequently treated are: a) globellar area of frown lines, located between the eyes; b) crow’s feet (lateral areas of the eyes); c) forehead wrinkles; d) radial lip lines (smokers lines); e) head and neck muscles. Botox is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. Patients may feel a slight burning sensation while the solution is being injected. The procedure takes about 15-20 minutes and the results can last up to 3 months. With repeated treatments, the results may tend to last longer.

RISKS AND COMPLICATIONS
Before undergoing this procedure, understanding the risks is essential. No procedure is completely risk-free. The following risks may occur, but there may be unforeseen risks and risks that are not included on this list. Some of these risks, if they occur, may necessitate hospitalization, and/or extended outpatient therapy to permit adequate treatment. It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to: 1. Post treatment discomfort, swelling, redness, and bruising. 2. Double vision, 3. A weakened tear duct, 4. Post treatment bacterial, and/or fungal infection requiring further treatment, 5. Allergic reaction, 6. Minor temporary droop of eyelid(s) in approximately 2% of injections, this usually lasts 2-3 weeks, 7. Occasional numbness of the forehead lasting up to 2-3 weeks, 8. Transient headache and 9. Flu-like symptoms may occur.

PREGNANCY, ALLERGIES & NEUROLOGIC DISEASE
I am not aware that I am pregnant and I am not trying to get pregnant, I am not lactating (nursing). I do not have any significant neurologic disease including but not limited to myasthenia gravis, multiple sclerosis, lambert-eaton syndrome, amyotrophic lateral sclerosis (ALS), and parkinson’s. I do not have any allergies to the toxin ingredients, to human albumin or eggs.

ALTERNATIVE PROCEDURES
Alternatives to the procedures and options that I have volunteered for have been fully explained to me.

PAYMENT
I understand that this is an “elective” procedure and that payment is my responsibility and is expected at the time of treatment.

RIGHT TO DISCONTINUE TREATMENT
I understand that I have the right to discontinue treatment at any time.

RESULTS
I am aware that when small amounts of purified botulinium toxin are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 2-10 days and usually lasts up to 3 months but can be shorter or longer. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual and there are some individuals who do not respond at all. I understand that I will not be able to use the muscles injected as before while the injection is effective but that this will reverse after a period of months at which time re=treatment is appropriate, I understand that I must stay in the erect posture and that I must not manipulate the area(s) of the injections for the 4 hours post-injection period.
I understand this is an elective procedure and I hereby voluntarily consent to treatment with botulinum toxin injections for facial dynamic wrinkles, TMJ dysfunction, bruxism and types of orofacial pain, including headaches and migraines. The procedure has been fully explained to me. I also understand that any treatment performed is between me and the doctor/healthcare provider who is treating me and I will direct all post-operative questions or concerns to the treating clinician. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure and I understand that no guarantees are implied to the outcome of the procedure. I also certify that if I have any changes in my medical history I will notify the doctor/healthcare professional who treated me immediately. I also state that I read and write in English.

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I am the treating healthcare professional, I discussed the above risks, benefits, and alternatives with the patient. The patient had an opportunity to have all questions answered and was offered a copy of this formed consent. The patient has been told to contact my office should they have any questions or concerns after this treatment procedure.

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Read the Medication Guide that comes with BOTOX® or BOTOX® Cosmetic before you start using it and each time it is given to you. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information I should know about BOTOX and BOTOX Cosmetic?

BOTOX and BOTOX Cosmetic may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX or BOTOX Cosmetic:

- Problems swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of BOTOX or BOTOX Cosmetic usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with BOTOX or BOTOX Cosmetic.
- People with certain breathing problems may need to use muscles in their neck to help them breathe. These patients may be at greater risk for serious breathing problems with BOTOX or BOTOX Cosmetic.
- Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving BOTOX or BOTOX Cosmetic have the highest risk of getting these problems.
- 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.

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
• 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.
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