

Medication Guide
BOTOX®
BOTOX® Cosmetic
(Botox)
(onabotulinumtoxinA)
for injection

These problems can happen hours, days, to weeks after an injection of BOTOX and BOTOX Cosmetic. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX or BOTOX Cosmetic:

- 1. Problems swallowing, speaking, or breathing.** These problems can happen hours, days, 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 people 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.
- 2. 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, days, 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 chronic migraine, severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX Cosmetic** has been used at the recommended dose to treat frown lines and/or crow's feet lines.

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** or **BOTOX Cosmetic**.
- Had an allergic reaction to any other botulinum toxin product such as *Myobloc*®, *Dysport*®, or *Xeomin*®
- Have a skin infection at the planned injection site
- Are being treated for urinary incontinence and have a urinary tract infection (UTI)
- Are being treated for urinary incontinence and find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing)

Why 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**?"
- Have allergies to any botulinum toxin product
- Had any side effect from any botulinum toxin product in the past
- Have or have had a breathing problem, such as asthma or emphysema
- Have or have had swallowing problems
- Have or have had bleeding problems
- Have plans to have surgery
- Had surgery on your face
- Have weakness of your forehead muscles, such as trouble raising your eyebrows
- Have drooping eyelids
- Have any other change in the way your face normally looks
- Have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence. Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever.
- Have problems emptying your bladder on your own and are being treated for urinary incontinence
- 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), *Dysport* (abobotulinumtoxinA), or *Xeomin* (incobotulinumtoxinA) in the past. Be sure your doctor knows exactly which product you received.
- Have recently received an antibiotic by injection
- Take muscular relaxants
- Take an allergy or cold medicine

- Take a sleep medicine
- Take anti-platelets (aspirin-like products) and/or anti-coagulants (blood thinners)

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.

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.

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.
- Urinary tract infection in people being treated for urinary incontinence
- Painful urination in people being treated for urinary incontinence
- Inability to empty your bladder on your own and are being treated for urinary incontinence. If you have difficulty fully emptying your bladder after getting **BOTOX**, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.
- 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.

BOTOX INFORMED CONSENT

AREA (S) BEING TREATED ARE OFF LABEL

Client name (print): _____ Age: _____

To the Client: You have the right to be informed about your skin condition and the treatment you are about to receive. After knowing the risks and hazards involved, you must make the decision whether or not to undergo the procedure. This disclosure is not meant to scare or alarm you. We want you to make an informed decision.

I have requested that Image Skin Institute improve my facial expression lines with Botox/Dysport. These are Botulinum Toxins. These injections have been used for more than a decade in children and adults to improve the problem of muscle spasm in facial muscles. These have also been useful to correct double vision due to muscle imbalance. Injection of minor amounts weakens the muscle and diminishes frown lines, crow's feet and facial expression lines. Although the results are usually dramatic, I have been informed that the practice of medicine is not an exact science and that no guarantees can be or have been made concerning expected results in my case. Initial if you understand and agree _____

The solution is injected with a small needle into the muscle. Improvement in injected areas will occur within **TWO WEEKS**. If the results are not satisfactory at two weeks, please call to schedule an appointment for possible re-injection. If this is your first Botox/Dysport treatment at Image Skin Institute and you require more than five (5) units of Botox during your first follow-up visit, the charge will be **\$10.99** per unit.

and agree _____

Initial if you understand

Side effects and complications have been minimal. Occasionally, slight swelling and/or bruising may last for several days after injections. Rarely, an adjacent muscle may be weakened for several weeks after an injection. Intractable headaches (migraine-like) lasting three to four weeks have been reported in 1% of the population receiving Botox/Dysport. I have been advised of the risks involved in such treatment, the expected benefits of such treatment and alternative treatments, including no treatment at all.

Botox cosmetic may cause serious side effects that can be life threatening, including: problems bleeding or swallowing, spread of toxins may occur hours, days to weeks after the injection.

Initial if you understand and agree _____

I understand that several sessions may be needed to maintain the desired results. and agree _____

Initial if you understand

I agree that this constitutes full disclosure and that it supersedes any previous verbal or written disclosure. I certify that I have read and fully understand the above paragraphs and that I have had sufficient opportunity for discussion and to ask questions.

Initial if you understand and agree _____

Staff Signature
Date

Client Signature

Staff Signature
Date

Client Signature

Staff Signature
Date

Client Signature

RECOMMENDED MINIMUM BOTOX/DYSPORT UNITS FOR "FIRST TIME" CLIENTS

	<i>Botox</i>	<i>Dysport</i>
Glabella (between brows)	20 units	50 units
Orbicularis Oculi (eyes)	20 units	50 units
Eye Brow	2 units each brow	5 units
Inferior Medial Orbicularis (upper lip)	4 units	10 units
Inferior Medial Orbicularis (lower lip)	2 units	5 units
Frontalis (forehead)	20 units	50 units
Depressor Angularis (corners of mouth)	4 units	10 units
Platysma (neck)	10 units	25 units
Mentalis (chin)	2 units	5 units

