



## Getting Your Child Started on BOTOX<sup>®</sup>

Learn how BOTOX<sup>®</sup> can help children 2 to 17 years of age with Pediatric Spasticity

### Indication

BOTOX<sup>®</sup> is a prescription medicine that is injected into muscles to treat increased muscle stiffness in people 2 years of age and older with spasticity.

BOTOX<sup>®</sup> has not been shown to help people perform task-specific functions with their upper limbs or increase movement in joints that are permanently fixed in position by stiff muscles.

### IMPORTANT SAFETY INFORMATION

**BOTOX<sup>®</sup> may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX<sup>®</sup>:**

- **Problems 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
- **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 loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing

**Please see additional Indications and Important Safety Information inside.**

## What is spasticity?

Spasticity is a debilitating condition that causes muscles in the arms and legs to involuntarily tense up, causing:

- Muscle tightness and stiffness
- Uncontrollable twitches or spasms

Nearly  
**80%**  
of children with cerebral palsy have spasticity

(N = 451)



BOTOX® is an important treatment option for children 2 to 17 years of age experiencing spasticity associated with cerebral palsy or stroke.

### Indications (continued)

BOTOX® is a prescription medicine that is injected into muscles and used to treat certain types of eye muscle problems (Strabismus) or abnormal spasm of the eyelids (Blepharospasm) in people 12 years and older.

### IMPORTANT SAFETY INFORMATION (continued)

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 Blepharospasm or Strabismus.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

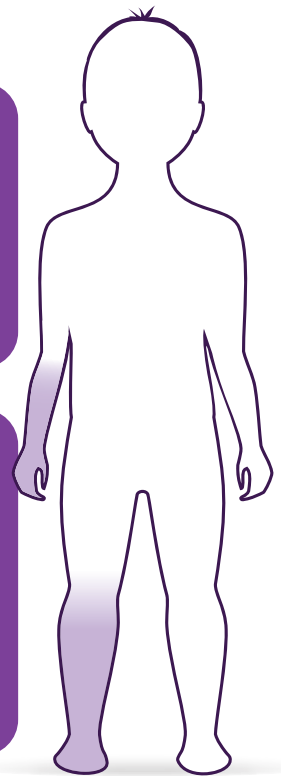
**Do not receive BOTOX® if you:** are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site.

## What is BOTOX®?

BOTOX® is approved by the FDA to treat spasticity of the arms and legs in children 2 to 17 years of age. Doctors have been using it to help people 12 years and older since 1989 when it was approved to treat certain types of eye muscle problems (Strabismus) or abnormal spasm of the eyelids (Blepharospasm).

BOTOX® works by temporarily blocking nerve signals that cause muscle stiffness. This helps reduce spasticity in your child's arms and/or legs

BOTOX® is injected by a doctor directly into stiff muscles of the arms and/or legs that are affected by spasticity. This is different from other oral medications your child may take



### IMPORTANT SAFETY INFORMATION (continued)

**The dose of BOTOX® is not the same as, or comparable to, another botulinum toxin product.**

**Serious and/or immediate allergic reactions have been reported,** including itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

**Please see additional Important Safety Information about BOTOX® on following pages.**

## What should you and your child expect from BOTOX<sup>®</sup> treatment?



Treatment takes place in an office or hospital, depending on your child's needs.

Fine needles are used, but they may cause some discomfort.



Affected muscles are injected.

You and your child may notice results within 4 to 6 weeks after injection.



BOTOX<sup>®</sup> is not a cure. Your child may need to return for retreatment no sooner than 12 weeks after the previous treatment, as determined by your child's doctor.

### IMPORTANT SAFETY INFORMATION (continued)

**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<sup>®</sup>.

**Tell your doctor if you have any breathing-related problems.** Your doctor may monitor you for breathing problems during treatment with BOTOX<sup>®</sup> for spasticity. The risk of developing lung disease in patients with reduced lung function is increased in patients receiving BOTOX<sup>®</sup>.

**Please see additional Important Safety Information about BOTOX<sup>®</sup> on following pages.**

## How can you save on the cost of BOTOX<sup>®</sup> for your child?



**BOTOX**<sup>®</sup>  
**SAVINGS**  
PROGRAM

Parents of patients may

**PAY \$0** for BOTOX<sup>®</sup> treatments  
as little as

By participating in the BOTOX<sup>®</sup> Savings Program, you acknowledge and agree to the full Terms & Conditions set out at [BOTOXSavingsProgram.com/TermsandConditions](http://BOTOXSavingsProgram.com/TermsandConditions). Patients enrolled in Medicare, Medicaid, TRICARE, or any other government reimbursed healthcare program are not eligible. Other restrictions and maximum limits apply.

Most commercial insurance plans cover the majority of BOTOX<sup>®</sup> costs for approved indications. But if you have remaining out-of-pocket costs, the BOTOX<sup>®</sup> Savings Program may reimburse you for them.

Text\* **SAVE to 27747** or visit  
**[BOTOXSavingsProgram.com](http://BOTOXSavingsProgram.com)** to get started

\*See Privacy & Terms: [BOTOXSavingsProgram.com/eligibility](http://BOTOXSavingsProgram.com/eligibility). Message & data rates may apply. Message frequency may vary. Text HELP for help, STOP to end.

## What questions should you ask your child's doctor?



Use every opportunity to better understand all aspects of BOTOX<sup>®</sup>.

### Here are some questions you may want to ask:

- What can my child expect from BOTOX<sup>®</sup> treatment and when will we see results?
- What's your personal experience with BOTOX<sup>®</sup>?
- How should I explain BOTOX<sup>®</sup> therapy to my child?
- Can I stay with my child during treatment?
- Where will BOTOX<sup>®</sup> be injected?
- How small are the needles used for injection?
- How long will the procedure take?
- How can we make my child comfortable for the procedure?
- What do the injections feel like?
- When will my child come back for retreatment?
- What are the possible side effects?

### IMPORTANT SAFETY INFORMATION (continued)

**Cornea problems have been reported.** Cornea (surface of the eye) problems have been reported in some people receiving BOTOX<sup>®</sup> for their Blepharospasm, especially in people with certain nerve disorders. BOTOX<sup>®</sup> may cause the eyelids to blink less, which could lead to the surface of the eye being exposed to air more than is usual. Tell your doctor if you experience any problems with your eyes while receiving BOTOX<sup>®</sup>. Your doctor may treat your eyes with drops, ointments, contact lenses, or with an eye patch.

**Bleeding behind the eye has been reported.** Bleeding behind the eyeball has been reported in some people receiving BOTOX<sup>®</sup> for their Strabismus. Tell your doctor if you notice any new visual problems while receiving BOTOX<sup>®</sup>.

**Upper respiratory tract infections (common colds) have been reported.** In pediatric patients treated with BOTOX<sup>®</sup> for upper limb spasticity, upper respiratory tract infections were reported more frequently. In pediatric patients treated with BOTOX<sup>®</sup> for lower limb spasticity, upper respiratory tract infections were not reported more frequently than placebo.

## What are the possible side effects?



These are the most common side effects seen in clinical studies for Pediatric Spasticity

### Upper Limb Spasticity:

- Upper respiratory tract infection\*
- Stuffy and runny nose
- Injection-site pain
- Constipation
- Nausea
- Seizure<sup>†</sup>

### Lower Limb Spasticity:

- Skin redness or pain at the injection site
- Mouth or throat pain
- Joint sprain
- Skin wounds
- Decreased appetite

\*Includes viral upper respiratory tract infection.  
<sup>†</sup>Includes partial seizure.

These occurred in  $\geq 2\%$  of patients treated with BOTOX<sup>®</sup> at 6 Units/kg (Pediatric Upper Limb Spasticity) or 8 Units/kg (Pediatric Lower Limb Spasticity).

This list does not cover all the possible serious side effects of BOTOX<sup>®</sup>. Please see the Summary of Information about BOTOX<sup>®</sup>, the Important Safety Information, and talk to your child's doctor.

### IMPORTANT SAFETY INFORMATION (continued)

**Tell your doctor about all your medical conditions, including if you:** have or have had bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX<sup>®</sup> can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX<sup>®</sup> passes into breast milk).

**Please see additional Important Safety Information about BOTOX<sup>®</sup> on following pages.**

# What does a BOTOX<sup>®</sup> treatment plan look like?



## First treatment

- The doctor may discuss treatment goals with you and your child and help set realistic expectations
- The doctor may explain that it could take more than 1 treatment to determine the muscles and BOTOX<sup>®</sup> dose that is right for your child
- Before leaving the office, you may want to schedule your child's follow-up appointment. You can also schedule their retreatment appointment if the doctor recommends another treatment session



## Between treatments

- The doctor may ask you to return for a follow-up visit about 4-6 weeks after your child's first treatment to see how they have responded to BOTOX<sup>®</sup>
- The office may confirm your child's next treatment appointment before you leave if the doctor recommends retreatment



## Additional treatments

- If your child's doctor recommends retreatment, he/she will advise you on when to come back (generally no sooner than 12 weeks after the first treatment)
- You may want to use this time to tell the doctor about any changes in your child's spasticity, such as reduced muscle tightness. It's a good idea to be open, honest, and to share as much information as possible
- Based on what is shared, the doctor may decide on the best course of action for any future treatment sessions
- Before leaving, you may want to schedule your child's next follow-up visit as well as their next treatment session, depending on what the doctor has recommended

### **IMPORTANT SAFETY INFORMATION** (continued)

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX<sup>®</sup> 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<sup>®</sup> in the past.**

**Please see additional Important Safety Information about BOTOX<sup>®</sup> on following pages.**



## Questions between visits?

Don't hesitate to call your doctor.



# Are there patient organizations that offer support?

There are many groups that advocate for patients and can offer additional guidance and resources.



## Cerebral Palsy Foundation

YourCPF.org  
info@yourcpf.org



## Child Neurology Foundation

ChildNeurologyFoundation.org  
info@childneurologyfoundation.org



## United Cerebral Palsy (UCP)

UCP.org



**BOTOX**<sup>®</sup>  
onabotulinumtoxinA injection

### **BOTOX<sup>®</sup> Savings Program Terms and Conditions**

**Program Terms, Conditions, and Eligibility Criteria:** **1.** Offer good only with a valid prescription for BOTOX<sup>®</sup> (onabotulinumtoxinA). **2.** Based on insurance coverage, reimbursement may be up to \$1000 per treatment with a maximum savings limit of \$4000 per year; patient out-of-pocket expense may vary. **3.** Offer not valid for (a) patients enrolled in Medicare, Medicaid, TRICARE or any other government-reimbursed healthcare program (including any state pharmaceutical assistance programs), or private indemnity or HMO insurance plans that reimburse for the entire cost of prescription drugs; (b) patients who are Medicare-eligible and enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees; (c) cash-paying patients. **4.** Offer valid for up to 4 treatments over a 12-month period; offer is valid for a 5th treatment for Chronic Migraine. **5.** Offer valid only for BOTOX<sup>®</sup> and BOTOX<sup>®</sup> treatment-related costs not covered by insurance. For residents of Massachusetts, Michigan, Minnesota, and Rhode Island, offer applies only to the cost of BOTOX<sup>®</sup> and not to any related medical service(s). **6.** Claims must be submitted within 180 days of treatment date and must include a copy of (a) an Explanation of Benefits (EOB) for the BOTOX<sup>®</sup> treatment, (b) a Specialty Pharmacy (SP) receipt for BOTOX<sup>®</sup>, or (c) other writing showing payment of out-of-pocket BOTOX<sup>®</sup> and treatment-related out-of-pocket costs. **7.** A BOTOX<sup>®</sup> Savings Program check will be provided upon approval of a claim and may be sent either directly to you or to your authorized healthcare provider who provided treatment. For payment to be made to your healthcare provider, an authorized assignment of benefit also must be included with the Claim. Assigning your BOTOX<sup>®</sup> Savings Program benefit to your healthcare provider is not required to participate in the program. **8.** Allergan<sup>®</sup> reserves the right to rescind, revoke, or amend this offer without notice. **9.** Offer good only in the USA, including Puerto Rico, at participating retail locations. **10.** Void where prohibited by law, taxed, or restricted. **11.** Offer does not constitute health insurance. **12. By participating in the BOTOX<sup>®</sup> Savings Program, you acknowledge and agree to the terms and conditions of this program.**

For questions about this program, please call 1-800-44-BOTOX.

These organizations are potential resources and are not endorsed by Allergan, an AbbVie company

### **IMPORTANT SAFETY INFORMATION (continued)**

Tell your doctor if you received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*<sup>®</sup>, *Dysport*<sup>®</sup>, or *Xeomin*<sup>®</sup> 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.

**Other side effects of BOTOX<sup>®</sup> 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, dry eyes; drooping eyebrows; and upper respiratory tract infection.

**Please see additional Important Safety Information about BOTOX<sup>®</sup> on back cover.**

**BOTOX**<sup>®</sup>  
onabotulinumtoxinA injection

# Trust BOTOX<sup>®</sup> for your child's spasticity

BOTOX<sup>®</sup> has been helping people since 1989



Following initial US approval of Blepharospasm/Strabismus  
in people 12 years and older



BOTOX<sup>®</sup> is the **world's most-studied**  
medicine of its class

BOTOX<sup>®</sup> is FDA approved to  
treat **11 conditions**—the most  
of any medicine in its class



BOTOX<sup>®</sup> is approved to treat  
people in **98 countries**

**Talk to your child's doctor  
about BOTOX<sup>®</sup> today.**

#### **IMPORTANT SAFETY INFORMATION (continued)**

For more information refer to the Medication Guide or talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA.  
Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see accompanying Summary of Information about BOTOX<sup>®</sup>**



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**Summary of Information about BOTOX® (onabotulinumtoxinA) for injection, for intramuscular, intradetrusor or intradermal use**

**What is the most important information I should know about BOTOX®?**

**BOTOX® 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 any time (hours to weeks) after injection of BOTOX®:**

- **Problems 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 preexisting before injection. Swallowing problems may last for several months
- **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; drooping eyelids; hoarseness or change or loss of voice; trouble saying words clearly; loss of bladder control; trouble breathing; and trouble swallowing

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.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of receiving BOTOX®. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

**BOTOX® dosing units are not the same as, or comparable to, any other botulinum toxin product.**

**What is BOTOX®?**

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

- To treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency) in adults 18 years and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken
- To treat leakage of urine (incontinence) in adults 18 years and older with overactive bladder due to a neurologic disease when another type of medicine (anticholinergic) does not work well enough or cannot be taken
- To treat overactive bladder due to a neurologic disease in children 5 years of age and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken
- To prevent headaches in adults with Chronic Migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older
- To treat increased muscle stiffness in people 2 years of age and older with spasticity
- To treat the abnormal head position and neck pain that happens with Cervical Dystonia (CD) in people 16 years and older

- To treat certain types of eye muscle problems (Strabismus) or abnormal spasm of the eyelids (Blepharospasm) in people 12 years of age 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 in people 18 years and older.

It is not known whether BOTOX® is safe and effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

BOTOX® has not been shown to help people perform task-specific functions with their upper limbs or increase movement in joints that are permanently fixed in position by stiff muscles.

It is not known whether BOTOX® is safe and effective for severe sweating anywhere other than your armpits.

**Who should not receive BOTOX®?**

Do not receive BOTOX® if you are allergic to any of the ingredients in BOTOX® such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); have a skin infection at the planned injection site; have a urinary tract infection (UTI); or find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing).

**What should I tell my doctor before treatment?**

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.

Tell your doctor if you have or have had breathing problems such as asthma or emphysema; swallowing problems; bleeding issues; surgery or plan to have surgery; forehead muscle weakness such as trouble raising your eyebrows; drooping eyelids; or any changes to your face; symptoms of a urinary tract infection, or UTI, (symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever); problems emptying your bladder on your own.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding, or plan to breastfeed. It is not known if BOTOX® can harm your unborn baby or if BOTOX® passes into breast milk.

**What are common side effects?**

Overactive bladder:

In adults, the most common side effects include urinary tract infection, painful urination, and the temporary inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX®, you may need to use a small disposable self-catheter to empty your bladder up to a few times each day until your bladder is able to start emptying again.

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Overactive bladder caused by a neurologic condition:

In adults, the most common side effects include urinary tract infection and the temporary inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX®, you may need to use a small disposable self-catheter to empty your bladder up to a few times each day until your bladder is able to start emptying again.

Overactive bladder caused by a neurologic condition in children 5 years of age and older:

The most common side effects include bacteria in the urine, urinary tract infection, leukocyturia (white blood cells in the urine), and hematuria (blood in the urine).

Chronic Migraine:

The most common side effects include neck pain; headache; migraine; slight or partial facial paralysis; eyelid drooping; bronchitis; musculoskeletal stiffness; muscular weakness; pain in 1 or more muscles, ligaments, tendons, or bones; muscle spasms; discomfort or pain at the injection site; and high blood pressure.

Adult Upper Limb Spasticity:

The most common side effects include nausea, tiredness, bronchitis, pain in extremity, and muscle weakness.

Adult Lower Limb Spasticity:

The most common side effects include joint pain, back pain, muscle pain, upper respiratory tract infection, and injection-site pain.

Pediatric Upper Limb Spasticity:

The most common side effects include upper respiratory tract infection (includes viral upper respiratory tract infection), stuffy or runny nose, injection-site pain, constipation, nausea, and seizure (includes partial seizure).

Pediatric Lower Limb Spasticity:

The most common side effects include injection-site erythema, injection-site pain, oropharyngeal pain, ligament sprain, skin abrasion, and decreased appetite.

Cervical Dystonia:

The most common side effects include difficulty swallowing, upper respiratory infection, neck pain, tiredness, muscle pain, joint pain, and headache.

Strabismus:

The most common side effects include droopy eyelid and upward drifting of the eye. Other side effects include double vision, blurred vision, decreased eyesight, swelling of the eyelid, dry eye, and drooping eyebrows.

Blepharospasm:

The most common side effects include droopy eyelid, swelling of the cornea (surface of the eye), dry eye, tearing, and irritation. Other side effects include double vision, blurred vision, decreased eyesight, and drooping eyebrows.

Severe Underarm Sweating:

The most common side effects include discomfort or pain at the injection site and hemorrhage, non-axillary sweating, infection, pharyngitis, flu syndrome, headache, fever, neck or back pain, pruritus, and anxiety.

Other side effects have been reported including, allergic reactions (eg, itching, rash, red itchy welts, wheezing, asthma symptoms, dizziness, or feeling faint), dry mouth, and drooping eyelids.

These are not all of the possible side effects. Call your doctor for medical advice if you experience any side effects after treatment with BOTOX®.

**What should I tell my doctor about prescription and over-the-counter medicines I take?**

Using BOTOX® 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® in the past.** Tell your doctor if you have received an injection with another botulinum toxin product in the last 4 months, such as Myobloc®, Dysport®, or Xeomin®. Be sure your doctor knows which product you received.

Tell your doctor about all prescription and over-the-counter medicines, vitamins, and herbal supplements you take; recent antibiotic injections; anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products; and blood thinners.

**Ask your doctor if you are not sure whether your medicine is listed above.**

**To learn more**

If you would like more information, talk to your doctor and/or go to BOTOX.com for full Product Information, including Medication Guide.

You may report side effects to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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