BOTOX®
onabotulinumtoxinA injection

Use evidence-based BOTOX® muscle/dose selections for common Spasticity postures

ADULT UPPER LIMB SPASTICITY (ULS)[1-3]		
Flexed Elbow	• Biceps brachii • Brachialis	• Brachioradialis • Pronator teres
Pronated/ Supinated Forearm	• Pronator teres (pronation) • Pronator quadratus (pronation)	• Biceps brachii (supination)
Flexed Wrist	• Flexor carpi radialis • Flexor carpi ulnaris • Flexor digitorum superficialis (sublimis)	• Flexor digitorum profundus • Flexor pollicis longus
Flexed Fingers	• Flexor digitorum superficialis (sublimis) • Flexor digitorum profundus	• Lumbricals • Interossei
Thumb in Palm	• Flexor pollicis longus • Flexor pollicis brevis	• Opponens pollicis • Adductor pollicis
Intrinsic Plus Hand	• Lumbricals	• Interossei

ADULT LOWER LIMB SPASTICITY (LLS)[1,2,4,5]			
Equinovarus Foot	• Gastrocnemius	• Soleus	• Tibialis posterior
Flexed Ankle	• Gastrocnemius • Flexor hallucis longus	• Tibialis posterior • Flexor digitorum longus	• Soleus
Flexed Toes	• Flexor hallucis longus		• Flexor digitorum longus
Inverted/ Supinated Foot	• Tibialis posterior	• Flexor hallucis longus	• Flexor digitorum longus

Look inside for information on Pediatric Spasticity.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

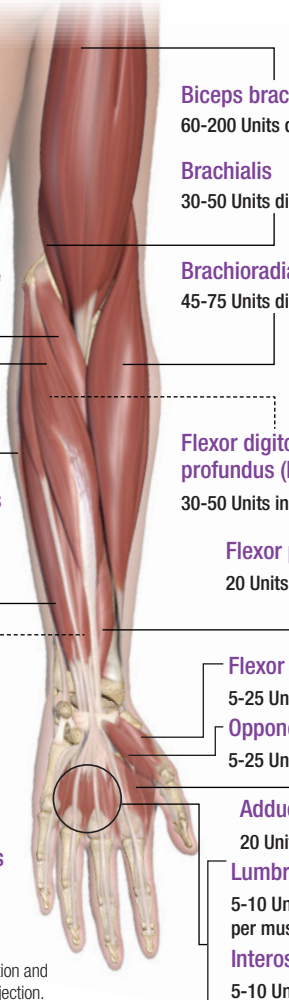
Postmarketing reports indicate that the effects of BOTOX and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening, and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses.

Please see Indications, Limitations of Use, and additional Important Safety Information inside.

BOTOX®
onabotulinumtoxinA injection

Adult Upper Limb Spasticity[1]

Use patient presentation and goals to determine proper dosing



Biceps brachii
60-200 Units divided in 2-4 sites

Brachialis
30-50 Units divided in 1-2 sites

Pronator teres
15-25 Units in 1 site

Brachioradialis
45-75 Units divided in 1-2 sites

Flexor carpi radialis
12.5-50 Units in 1 site

Flexor digitorum profundus (hidden)
30-50 Units in 1 site

Flexor carpi ulnaris
12.5-50 Units in 1 site

Flexor pollicis longus
20 Units in 1 site

Flexor digitorum superficialis (sublimis)
30-50 Units in 1 site

Flexor pollicis brevis
5-25 Units in 1 site

Opponens pollicis
5-25 Units in 1 site

Adductor pollicis
20 Units in 1 site

Pronator quadratus (hidden)
10-50 Units in 1 site

Lumbricals
5-10 Units in 1 site per muscle

Interossei
5-10 Units in 1 site per muscle

Lines indicate muscle location and do not point out sites for injection.

In Adult Upper Limb Spasticity clinical trials, 75-400 Units were divided among selected muscles[1]

INDICATIONS

Spasticity

BOTOX® (onabotulinumtoxinA) for injection is indicated for the treatment of spasticity in patients 2 years of age and older.

Limitations of Use

BOTOX has not been shown to improve upper extremity functional abilities or range of motion at a joint affected by a fixed contracture.

Cervical Dystonia

BOTOX is indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Spread of Toxin Effect

See *Boxed Warning*.

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX to the site of injection and/or adjacent structures. In several of the cases, patients had preexisting dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX. The safety and effectiveness of BOTOX for unapproved uses have not been established.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently, the causal agent cannot be reliably determined.

Increased Risk of Clinically Significant Effects With Preexisting Neuromuscular Disorders

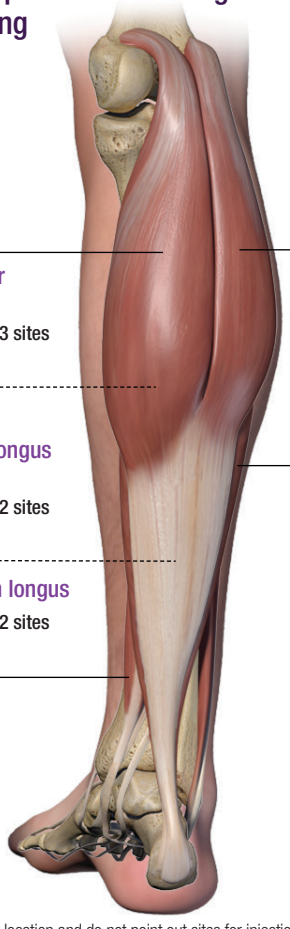
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects, including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX (see *Warnings and Precautions*).

Please see additional Important Safety Information on following pages.

BOTOX®
onabotulinumtoxinA injection

Adult Lower Limb Spasticity[1]

Use patient presentation and goals to determine proper dosing



Gastrocnemius (medial head)
75 Units
divided in 3 sites

Gastrocnemius (lateral head)
75 Units
divided in 3 sites

Tibialis posterior (hidden)
75 Units divided in 3 sites

Soleus
75 Units
divided in 3 sites

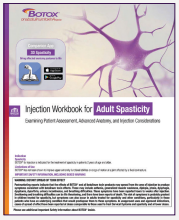
Flexor hallucis longus (hidden)
50 Units divided in 2 sites

Flexor digitorum longus
50 Units divided in 2 sites

Lines indicate muscle location and do not point out sites for injection.

The recommended dose for Adult Lower Limb Spasticity is 300-400 Units divided among the 5 muscles[1]

In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 Units in a 3-month period[1]



3D Spasticity®

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IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Dysphagia and Breathing Difficulties
Treatment with BOTOX and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with preexisting swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pulmonary Effects of BOTOX in Patients With Compromised Respiratory Status Treated for Spasticity
Patients with compromised respiratory status treated with BOTOX for spasticity should be monitored closely.

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity
Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult patients with reduced lung function treated for upper limb spasticity, upper respiratory tract infections were also reported more frequently as adverse reactions in patients treated with BOTOX (11% at 360 Units total dose; 8% at 240 Units total dose) compared to placebo (6%). In adult patients treated for lower limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX (2% at 300 Units to 400 Units total dose) compared to placebo (1%). In pediatric patients treated for upper limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX (17% at 6 Units/kg and 10% at 3 Units/kg) compared to placebo (9%). In pediatric patients treated for lower limb spasticity, upper respiratory tract infection was not reported with an incidence greater than placebo.

Human Albumin and Transmission of Viral Diseases
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Please see additional Important Safety Information on following pages.

BOTOX®
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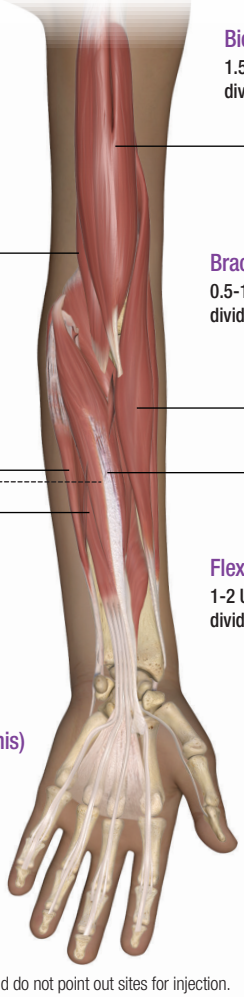
Pediatric Upper Limb Spasticity[1]

The recommended dose is 3-6 Units/kg divided among affected muscles



Biceps brachii
1.5-3 Units/kg
divided in 4 sites

Brachialis
1-2 Units/kg
divided in 2 sites

Brachioradialis
0.5-1 Unit/kg
divided in 2 sites

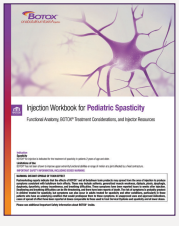
Flexor carpi ulnaris
1-2 Units/kg
divided in 2 sites

Flexor carpi radialis
1-2 Units/kg
divided in 2 sites

Flexor digitorum profundus (hidden)
0.5-1 Unit/kg
divided in 2 sites

Flexor digitorum superficialis (sublimis)
0.5-1 Unit/kg
divided in 2 sites

Lines indicate muscle location and do not point out sites for injection.



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The total dose administered per treatment session in the upper limb should not exceed 6 Units/kg or 200 Units, whichever is lower[1]

IMPORTANT SAFETY INFORMATION (continued)
ADVERSE REACTIONS
Adverse reactions to BOTOX for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Adult Upper Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

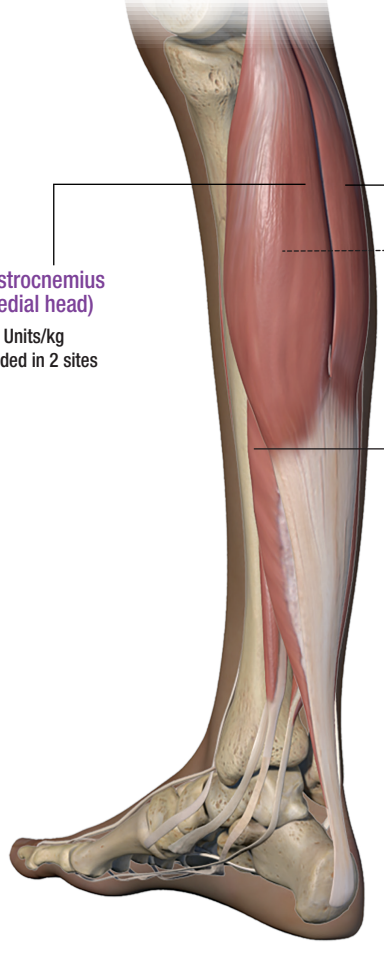
Adult Lower Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX for lower limb spasticity include arthralgia, back pain, myalgia, upper respiratory tract infection, and injection-site pain.

Please see additional Important Safety Information on following pages.

BOTOX® onabotulinumtoxinA injection

Pediatric Lower Limb Spasticity[1]

The recommended dose is 4-8 Units/kg divided among affected muscles



Lines indicate muscle location and do not point out sites for injection.

The total dose administered per treatment session in the lower limb should not exceed 8 Units/kg or 300 Units, whichever is lower[1]

In Pediatric Spasticity, when treating both lower limbs or the upper and lower limbs in combination, the total dose should not exceed the lower of 10 Units/kg or 340 Units in a 3-month interval[1]

IMPORTANT SAFETY INFORMATION (continued)
ADVERSE REACTIONS (continued)

Pediatric Upper Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX in pediatric upper limb spasticity include upper respiratory tract infection (includes upper respiratory tract infection and viral upper respiratory tract infection), injection-site pain, nausea, constipation, rhinorrhea, nasal congestion, and seizure (includes seizure and partial seizure).

Pediatric Lower Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX in pediatric lower limb spasticity include injection-site erythema, injection-site pain, oropharyngeal pain, ligament sprain, skin abrasion, and decreased appetite.

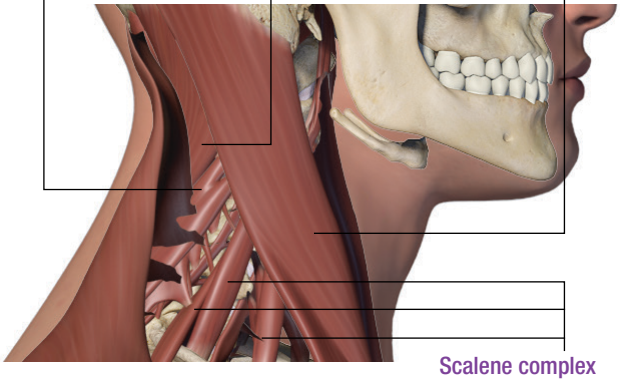
Cervical Dystonia
The most frequently reported adverse reactions following injection of BOTOX for cervical dystonia include dysphagia (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

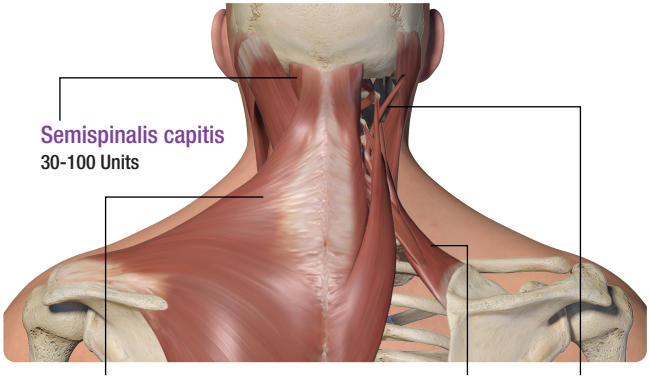
Please see additional Important Safety Information on following pages.

BOTOX®
onabotulinumtoxinA injection

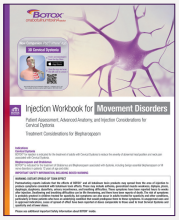
Cervical Dystonia[1,6]

Use patient presentation and goals to determine proper dosing





Lines indicate muscle location and do not point out sites for injection.



3D Cervical Dystonia

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236 Units = mean BOTOX® dose in CD pivotal trial[1]
(25th to 75th percentile ranges were 198-300 Units)

IMPORTANT SAFETY INFORMATION (continued)
ADVERSE REACTIONS (continued)
Postmarketing Experience
Adverse reactions that have been identified during postapproval use of BOTOX are discussed in greater detail in *Postmarketing Experience* (Section 6.3 of the Prescribing Information).

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

Please see additional Important Safety Information on following page.

Over 20 years of proven muscle selection and dosing in Cervical Dystonia[7]

CERVICAL DYSTONIA		
Torticollis (Rotation)	• Splenius capitis • Trapezius (upper) • Splenius cervicis • Longissimus (capitis/cervicis)	• Levator scapulae • Sternocleidomastoid • Anterior scalene
Laterocollis (Tilt)	• Splenius capitis • Trapezius (upper) • Splenius cervicis • Longissimus	• Levator scapulae • Sternocleidomastoid • Anterior/middle/ posterior scalenes
Anterocollis (Flexion)	• Anterior/middle scalenes	
Retrocollis (Extension)	• Semispinalis capitis • Splenius capitis • Trapezius (upper)	• Splenius cervicis • Longissimus • Levator scapulae

References: 1. BOTOX® Prescribing Information, July 2021. **2.** Standring S, ed. *Gray's Anatomy: The Anatomical Basis of Clinical Practice*. 41st ed. Churchill Livingstone; 2016. **3.** Washington University School of Medicine in St. Louis. Peripheral nerve surgery: a resource for surgeons. Flexor pollicis longus. Washington University School of Medicine in St. Louis website. Accessed 2022. https://nervesurgery.wustl.edu/ap/hand/median/anteriorinterosseousnerve/Pages/FlexorPollicisLongus.aspx **4.** Richardson M. Muscle atlas: Tibialis posterior. University of Washington website. Accessed 2022. http://rad.washington.edu/muscle-atlas/tibialis-posterior/ **5.** Murdock CJ, Munjal A, Agyeman K. Anatomy, Bony Pelvis and Lower Limb, Calf Flexor Hallucis Longus Muscle. In: *StatPearls*. StatPearls Publishing; October 5, 2021. **6.** Charles D, Gill CE. Neurotoxin injection for movement disorders. *Continuum Lifelong Learning Neurol*. 2010;16(1):131-157. **7.** Data on file, AbbVie Inc.

IMPORTANT SAFETY INFORMATION (continued)
DRUG INTERACTIONS

Co-administration of BOTOX and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX.

Please see additional Important Safety Information inside.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide, or visit https://www.rxabbvie.com/pdf/botox_pi.pdf.

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