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Botox

# Botox 🖘

Pronunciation: Boe-tox

Generic name: onabotulinumtoxinA

Brand name: Botox Therapeutic

Dosage form: single-dose vial (100 Units, 200 Units)

Drug class: Skeletal muscle relaxants

Medically reviewed by Carmen Pope, BPharm. Last updated on Apr 17, 2025.

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# What is Botox?

Botox is used to treat chronic migraines, excessive sweating, bladder conditions, eye muscle disorders, including strabismus, and other muscle or neck spasms. A healthcare provider injects tiny amounts of Botox into the specific muscles or glands being treated every 3 months or more, depending on the condition.

- The effects of Botox are temporary.
- Reinjection typically occurs once the benefits of the previous treatment have diminished, but treatments are generally
  not administered more frequently than every 3 months.

This guide covers Botox injection for medical use. Botox Cosmetic is used for cosmetic purposes to temporarily smooth wrinkles and platysma bands (vertical bands of tissue connecting the neck and jaw).

Botox (onabotulinumtoxinA, botulinum toxin type A) first gained FDA approval on December 9, 1991. There is no generic, but there are Botox alternatives.

# FDA Approvals and indications

Botox injections are used for medical purposes to:

- treat **overactive bladder symptoms**, such as urinary urgency, frequency, or incontinence, in adults when anticholinergics do not work well enough or cannot be taken
- treat **urinary incontinence** due to detrusor overactivity associated with a neurological condition (such as spinal cord injury, multiple sclerosis) in adults who have had an inadequate response or are intolerant of an anticholinergic medication
- treat **neurogenic detrusor overactivity (NDO)** in children 5 years of age and older when anticholinergics do not work well enough or cannot be taken
- prevent headaches in adults with chronic migraine who have 15 or more days each month with headaches lasting 4

or more hours each day

- treat increased muscle stiffness in people 2 years of age and older with spasticity
- treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults
- treat strabismus or blepharospasm in people 12 years of age and older
- treat severe underarm sweating (primary axillary hyperhidrosis) when topical treatments do not work well enough.

Botox Cosmetic is used for aesthetic purposes to smooth wrinkles and improve the appearance of neck bands.

 Although Botox and Botox Cosmetic contain the same active ingredient, onabotulinumtoxinA, they have different FDA-approved uses and vial strengths, and are not interchangeable.

# How quickly does Botox work?

Botox begins relaxing targeted muscles within 24 to 48 hours after the injection when used for medical conditions. Maximum muscle relaxation and full results are usually seen 2 weeks after an injection. The effects of Botox gradually wear off after 3 to 9 months as nerve signals recover or nerves regenerate and muscle function returns.

## How does Botox work?

Botox is a neurotoxin that temporarily blocks nerve signals to specific muscles or sweat glands. This targeted approach:

- Relaxes muscles
- Eliminates or reduces muscle spasms
- Improves bladder capacity and incontinence symptoms
- Improves eye alignment
- Prevents migraines
- Inactivates overactive sweat glands, reducing sweating.

Botox wears off with time as new nerve endings sprout and gradually reconnect with muscles or sweat glands, allowing them to work normally again in the treated area.

# Botox safety for medical conditions

Botox for medical conditions should only be injected by a trained healthcare provider who can ensure:

- · Sterile conditions
- Proper dosing and injection techniques to minimize side effects
- Comprehensive pre-treatment consultation
- Detailed aftercare instructions
- · Regular follow-up care.

## **Botox side effects**

The most common side effects of Botox for medical use are as follows.

At the injection site:

- · Bruising, pain, redness, or swelling
- Numbness or tenderness
- Small bumps or marks that typically resolve within a few hours to days
- Infection at the injection site.

General side effects (these vary depending on the medical condition being treated):

- · dry mouth
- tiredness
- headache
- · neck pain
- · mild weakness in the treatment area
- eye problems in those being treated with Botox for strabismus: double vision, blurred vision, decreased eyesight, drooping eyelids/eyebrows, swelling of your eyelids, and dry eyes
- allergic reactions, which may include symptoms such as 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 upper respiratory tract infection.

Other common side effects experienced by those being treated with Botox for bladder conditions are:

- · urinary tract infection in both children and adults
- · painful urination in adults
- bacteria, white blood cells, and blood in the urine of children
- inability to empty your bladder on your own.

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 can start emptying again.

Most of these side effects are temporary and resolve within a few days to weeks.

# Serious side effects and warnings

Rarely, Botox can cause the following serious side effects that can happen hours, days, to weeks after an injection, but require immediate medical attention:

- Spread of toxin effects (Boxed warning). In some cases, the effect of botulinum toxin A 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:
  - o loss of strength and muscle weakness all over the body
  - double vision, blurred vision and drooping eyelids

- o hoarseness or change or loss of voice (dysphonia)
- o trouble saying words clearly (dysarthria)
- o loss of bladder control
- trouble breathing
- trouble swallowing.

These problems could make it unsafe for you to drive a car or do other dangerous activities. There has not been a confirmed serious case of the 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.

Problems swallowing, speaking, or breathing. These problems can happen hours, days, to weeks after an
injection of Botox, 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.

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.

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 have the highest risk of developing these problems.

Call your healthcare provider or get emergency medical help if you have any of these problems after treatment with Botox:

- o Difficulty swallowing, speaking, or breathing
- Vision problems
- Muscle weakness spreading beyond the injection site
- Allergic reactions (itching, rash, wheezing).

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Botox. For more information, ask your doctor or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA1088.

Botox side effects (more detail)

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# Before taking

It is not known whether medical Botox injections are safe and effective in people younger than:

- 18 years of age for treatment of chronic migraine, overactive bladder with urinary incontinence, or hyperhidrosis
- 5 years of age for the treatment of overactive bladder due to a neurologic disease
- 16 years of age for the treatment of cervical dystonia
- 12 years of age for the treatment of strabismus or blepharospasm
- 2 years of age for the treatment of spasticity.

It is not known whether Botox is safe and effective:

- to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine)
- for severe sweating anywhere other than your armpits.

Do not receive Botox if you:

- are allergic to any of the ingredients in Botox or Botox Cosmetic. See the end of this Guide for a complete list of ingredients in Botox and Botox Cosmetic
- had an allergic reaction to any other botulinum toxin product such as Myobloc (rimabotulinumtoxinB), Dysport (abobotulinumtoxinA), Xeomin (incobotulinumtoxinA), Jeuveau (prabotulinumtoxinA-xvfs), Daxxify

(daxibotulinumtoxinA-lanm), or Letybo (letibotulinumtoxinA-wlbg). This may not be a complete list of all botulinum toxin products

• have a skin infection at the planned injection site.

Before receiving Botox, tell your healthcare provider 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)
- have allergies to any botulinum toxin product
- had any side effects 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 drooping eyelids
- have any other changes in the way your face normally looks
- · are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

# **Pregnancy**

It is not known if Botox can harm your unborn baby.

## **Breastfeeding**

It is not known if Botox passes into breast milk.

Botox pregnancy and breastfeeding warnings (more detail)

## How is Botox administered?

Botox is given by a healthcare provider as a series of tiny injections into the affected muscle(s) or skin.

- This treatment is injected directly into specific muscles, areas of skin, or the bladder.
- Your healthcare provider may change your dose of Botox until they find the best dose for you.
- The effects of Botox are temporary. Your healthcare provider will tell you how often you will receive your injections, but it is usually not more frequently than every 3 months.
- Botox patient tips (more detail)

# **Dosing Information**

Your healthcare provider will follow medical condition-specific dosing and administration recommendations. In a 3-month

interval, they should not exceed a total dose of:

- Adults: 400 Units
- Pediatrics: the lesser of 10 Units/kg or 340 Units.

The following dosage recommendations are from the Botox Therapeutic Package Insert:

- Overactive Bladder: Recommended total dose is 100 Units, as 0.5 mL (5 Units) injections across 20 sites into the
  detrusor muscle.
- Adult Detrusor Overactivity associated with a Neurologic Condition: Recommended total dose 200 Units, as 1 mL (~6.7 Units) injections across 30 sites into the detrusor.
- Pediatric Detrusor Overactivity associated with a Neurologic Condition: 0.5 mL injections across 20 sites into the detrusor.
  - o Greater than or equal to 34 kg: Recommended total dose is 200 Units
  - Less than 34 kg: Recommended total dose is 6 Units/kg
- Chronic Migraine: Recommended total dose 155 Units, as 0.1 mL (5 Units) injections per each site divided across 7 head/neck muscles.
- Adult Upper Limb Spasticity: Recommended total dose up to 400 Units divided among affected muscles.
- Adult Lower Limb Spasticity: Recommended total dose 300 Units to 400 Units divided across ankle and toe
  muscles.
- Pediatric Upper Limb Spasticity: Recommended total dose 3 Units/kg to 6 Units/kg (maximum 200 Units) divided among affected muscles.
- Pediatric Lower Limb Spasticity: Recommended total dose 4 Units/kg to 8 Units/kg (maximum 300 Units) divided among affected muscles.
- **Cervical Dystonia:** Base dosing on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; use lower initial dose in botulinum toxin naïve patients.
- Axillary Hyperhidrosis: 50 Units per axilla.
- Blepharospasm: 1.25 Units-2.5 Units into each of 3 sites per affected eye.
- Strabismus: The dose is based on prism diopter correction or previous response to treatment with Botox
- Detailed Botox dosage information

# What should I avoid while receiving Botox?

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

# What other drugs affect Botox?

Tell your doctor about all your medicines, including prescription and over-the-counter medicines, vitamins and herbal supplements. 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. 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), Xeomin (incobotulinumtoxinA), Jeuveau (prabotulinumtoxinA-xvfs), Daxxify (daxibotulinumtoxinA-lanm), or Letybo (letibotulinumtoxinA-wlbg) in the past. This may not be a complete list of all botulinum toxin products. 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
- take anti-platelets (aspirin-like products) or anti-coagulants (blood thinners).

Ask your doctor if you are not sure if your medicine 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.

# **Botox ingredients**

Active ingredient: onabotulinumtoxinA

Inactive ingredients: human albumin and sodium chloride.

Available as 100 Units or 200 Units as a vacuum-dried powder in a single-dose vial.

## **Manufacturer**

Botox is made by AbbVie, which acquired the previous manufacturer, Allergan, in 2020. AbbVie is headquartered in North Chicago, Illinois, USA.

## **Botox Biosimilars**

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

# Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There are 2 for Botox.

### Botox (onabotulinumtoxinA) - AbbVie Inc.

Formulation type	Strength
Single-Dose Vial	100 units
Single-Dose Vial	200 units
Single-Dose Vial	50 units <b>Discontinued</b>

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# **Popular FAQ**

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Where do they inject Botox for migraines?

Does Botox for migraines also help with wrinkles?

What is Daxxify, the recent FDA-alternative to Botox?

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How many units of Botox are used for migraines?

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### References

- 1. Botox Package Insert
- 2. Botox Prescribing Information

# More about Botox (onabotulinumtoxinA)

- Check interactions
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### **Professional resources**

- Botox prescribing information
- OnabotulinumtoxinA (AHFS Monograph)

## Other formulations

Botox Cosmetic

## Related treatment guides

- Cervical Dystonia
- Blepharospasm
- Chronic Migraine
- · Chronic Spasticity

## **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

### **DRUG STATUS**

### **Availability**

Rx Prescription only

**Pregnancy & Lactation** 

ം Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

10+ years FDA approved 1991

## **User Reviews & Ratings**

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