

# BOTOX

FDA HAS APPROVED AS A PRESCRIPTION MEDICINE THAT IS INJECTED TO IMPROVE THE LOOK OF CROW'S FEET + FROWN LINES IN ADULTS FOR A SHORT PERIOD OF TIME (TEMPORARY).

**BOTOX® and BOTOX® Cosmetic** contain the same active ingredient in the same formulation. Therefore adverse events observed with the use of **BOTOX®** also have the potential to be associated with the use of **BOTOX® Cosmetic**.

## **Botox Cosmetic can cause:**

+ Life threatening swallowing and breathing difficulties

### + **Death**

+ Pain in extremity

+ Increased cough

+ Injection site pain and **hemorrhage**

+ Flu syndrome

+ Non-axillary sweating

+ Dry eyes/mouth

+ New onset or recurrent **seizures**

+ Abdominal pain

+ Brachial plexopathy

+ Decreased hearing

+ Diarrhea

+ Ear noise

+ Erythema multiforme

+ Fever

+ Focal facial paralysis

+ **Glaucoma**

+ Localized numbness

+ Vomiting

+ Swelling of your eyelids

+ Spread of toxin effects: loss of strength and muscle weakness all over the body, double vision, blurred vision and **drooping eyelids**, urinary incontinence, hoarseness

or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control,

trouble breathing, trouble swallowing

+ Pharyngitis

+ Reduced blinking with corneal exposure, persistent epithelial defect and corneal ulceration

+ Tiredness

+ Arrhythmia/myocardial infarction with **fatal** outcomes

+ Madarosis (loss of eyelashes)

+ Itching

+ Rash

+ Red itchy welts

+ Wheezing

+ Asthma symptoms

+ Dizziness or feeling faint

+ Anaphylaxis

+ Urticaria

+ Soft tissue edema

+ Dyspnea

+ Loss of appetite

+ Malaise

+ Myalgia

+ Myasthenia gravis

+ Pruritus

+ Psoriasiform eruption

+ Retinal vein occlusion

+ Sweating

+ Syncope

+ Vertigo with nystagmus

+ Alopecia (baldness)

+ Swallowing problems may last for several months. People who cannot swallow well **may need a feeding tube** to receive food and water.

+ Dysuria

+ Urinary retention

+ Neck pain

+ Headache

+ Back pain

+ Rhinitis



## SOURCES FROM FDA + ALLERGAN PHARMACEUTICALS

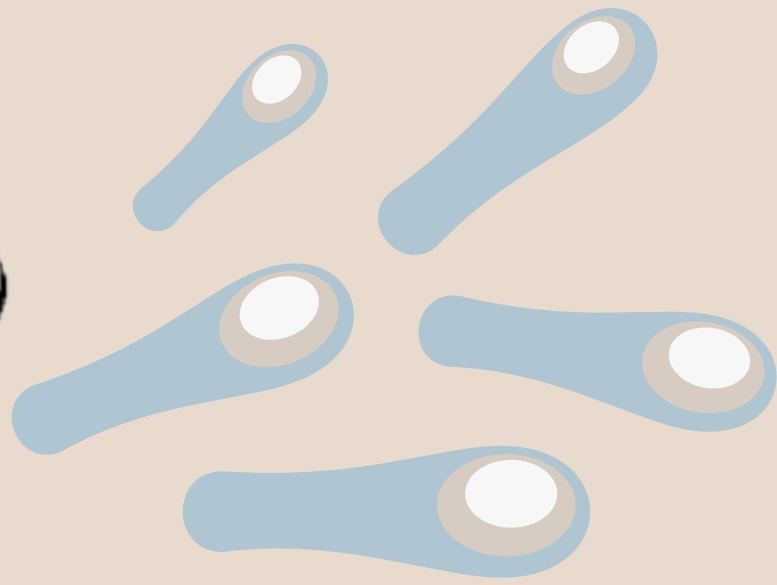
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# WHAT IS BOTOX COSMETIC?

**BOTOX® Cosmetic (onabotulinumtoxinA)** for injection, is a sterile, vacuum dried purified botulinum toxin type A, produced from fermentation of Hall strain *Clostridium botulinum* type A grown in a medium containing casein hydrolysate, glucose, and yeast extract, intended for intramuscular use. It is purified from the culture solution by dialysis and a series of acid precipitations to a complex consisting of the neurotoxin, and several accessory proteins. The complex is dissolved in sterile sodium chloride solution containing Albumin Human and is sterile filtered (0.2 microns) prior to filling and vacuum-drying.



Clostridium Botulinum

## HOW DOES IT WORK?

**BOTOX<sup>®</sup> Cosmetic** blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine. This inhibition occurs as the neurotoxin cleaves SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within nerve endings. When injected intramuscularly at therapeutic doses, BOTOX<sup>®</sup> Cosmetic produces partial chemical denervation of the muscle resulting in a localized reduction in muscle activity. In addition, the muscle may atrophy, axonal sprouting may occur, and extrajunctional acetylcholine receptors may develop. There is evidence that reinnervation of the muscle may occur, thus slowly reversing muscle denervation produced by **BOTOX<sup>®</sup> Cosmetic**.

*denervation:*

To deprive (an organ or body part) of a nerve supply, as by surgically removing or cutting a nerve or by blocking a nerve connection with drugs.

*reinnervation:*

The restoration of function to a denervated body part and especially a muscle by supplying it with nerves through regrowth.

## PRECAUTIONS

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The safe and effective use of **BOTOX<sup>®</sup> Cosmetic** depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. Physicians administering **BOTOX<sup>®</sup> Cosmetic** must understand the relevant neuromuscular and/or orbital anatomy of the area involved, as well as any alterations to the anatomy due to prior surgical procedures and avoid injection into vulnerable anatomic areas.

Administration of **BOTOX<sup>®</sup> Cosmetic** is not recommended during pregnancy. There are no adequate and well-controlled studies of **BOTOX<sup>®</sup> Cosmetic** in pregnant women. When pregnant mice and rats were injected intramuscularly during the period of organogenesis, the developmental NOEL (No Observed Effect Level) of **BOTOX<sup>®</sup> Cosmetic** was 4 Units/kg. Higher doses (8 Units/kg or 16 Units/kg) were associated with reductions in fetal body weights and/or delayed ossification.



If the patient becomes pregnant after the administration of this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations that have been observed in rabbits.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long term studies in animals have not been performed to evaluate carcinogenic potential of **BOTOX® Cosmetic**.

### **Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **BOTOX® Cosmetic** is administered to a nursing woman.

# THE CDC ON BOTULISM

Botulism (“BOT-choo-liz-um”) is a rare but serious illness caused by a toxin that attacks the body’s nerves and causes difficulty breathing, muscle paralysis, and even death. This toxin is made by *Clostridium botulinum* and sometimes *Clostridium butyricum* and *Clostridium baratii* bacteria. These bacteria can be spread by food and sometimes by other means.

The bacteria that make botulinum toxin are found naturally in many places, but it’s rare for them to make people sick. These bacteria make spores, which act like protective coatings. Spores help the bacteria survive in the environment, even in extreme conditions. The spores usually do not cause people to become sick, even when they’re eaten. But under certain conditions, these spores can grow and make one of the most lethal toxins known.

**Iatrogenic botulism** can happen if too much botulinum toxin is injected for cosmetic reasons, such as for wrinkles, or medical reasons, such as for migraine headaches.

<https://www.cdc.gov/botulism/general.html>

All kinds of botulism can be fatal and are medical emergencies. If you or someone you know has symptoms of botulism, see your doctor or go to the emergency room immediately.

Signs and symptoms might include:

- Difficulty swallowing
- Muscle weakness
- Double vision
- Drooping eyelids
- Blurry vision
- Slurred speech
- Difficulty breathing
- Difficulty moving the eyes



**People with botulism might not have all of these symptoms at the same time.**

The symptoms all result from muscle paralysis caused by the toxin. If untreated, the disease may progress and symptoms may worsen to cause full paralysis of some muscles, including those used in breathing and those in the arms, legs, and trunk (part of the body from the neck to the pelvis area, also called the torso).

<https://www.cdc.gov/botulism/symptoms.html>

# WHAT ABOUT OTHER BOTOX USES?

**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 when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease 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.
- to treat increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity.
- to treat increased muscle stiffness in ankle and toe muscles in adults with lower 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.

To read about the specific precautions for each FDA-approved usage, read the "Warnings and Precautions" (Section 5.0) in the Botox manufacturer insert located at the below FDA website.

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/103000s5302lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf)