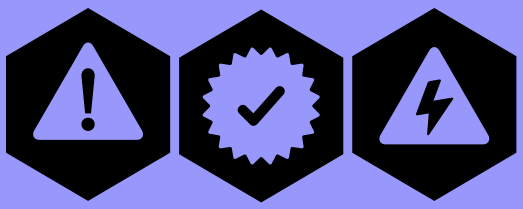
Unauthorized Product—The Risks Are Real

Know how to protect yourself and your patients from products of unknown origin



BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

Indications

BOTOX® Cosmetic (onabotulinumtoxinA) is indicated in adult patients for the temporary improvement in the appearance of:
- Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
- Moderate to severe lateral canthal lines associated with orbicularis oculi activity
- Moderate to severe forehead lines associated with frontalis activity
- Moderate to severe platysma bands associated with platysma muscle activity

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® Cosmetic 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 additional Important Safety Information on following pages.

The FDA Is Cracking Down on Illegal Activity

Over the past decade, the FDA Office of Criminal Investigations has been actively seeking to identify, warn, and even prosecute practitioners who utilize product that has been illegally imported into the United States.[1]

2013

Eleven people are charged in a case involving an unlicensed company accused of distributing misbranded prescription drugs, including injectable cosmetic drug products.[1]

2016

The owner of a skin rejuvenation practice pleaded guilty to a federal charge of receipt and delivery of a misbranded drug, which carries a penalty of up to 3 years in prison.[1]

2017

The proprietor of a medical aesthetics center in the midwest was charged with obtaining BOTOX® Cosmetic (onabotulinumtoxinA) as well as other botulinum products from foreign sources. If convicted she faces up to 3 years in federal prison.[1]

These are only a few examples of the consequences for physicians known to have purchased or received drugs from unlicensed and/or foreign supplies.

DID YOU KNOW?

When the FDA shuts down an illegal seller, it typically looks for the seller's customer list and contacts those practitioners.[1]

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX® Cosmetic is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Lack of Equivalency Between Botulinum Toxin Products

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

Spread of Toxin Effect

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 40 Units (for forehead lines with glabellar lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines), and 64 Units (for simultaneous treatment of lateral canthal lines, glabellar lines, and forehead lines) have been reported. Patients or caregivers should be advised to seek immediate medical care if swallowing, speech, or respiratory disorders occur.

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.

Protect Yourself

Know the consequences of purchasing, selling, and/or importing unauthorized product.

RISKS OF ILLEGALLY IMPORTED PRODUCT

Knowingly making, selling, or dispensing illegally imported botulinum toxin drug products may result in imprisonment for up to 10 years and a fine up to $250,000.[1]

BAIT AND SWITCH ADVERTISEMENT IS ILLEGAL

Advertising discounted prices on BOTOX® Cosmetic (onabotulinumtoxinA) and instead administeriwng a different neurotoxin or counterfeit product without consent is considered battery and may lead to imprisonment and/or fines.

PURCHASING PRODUCT THROUGH ANOTHER PROVIDER PUTS YOU AT RISK

This is unlawful business practice and is noncompliant with Allergan Aesthetics trademark rights and business practices.

DID YOU KNOW?

It's not a matter of *if* the FDA, medical licensing boards, and public will find out about illegal purchases, it's *when*.[1]

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, discontinue further injection of BOTOX Cosmetic and immediately institute appropriate medical therapy. 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.

Cardiovascular System
There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including preexisting cardiovascular disease. Use caution when administering to patients with preexisting cardiovascular disease.

Increased Risk of Clinically Significant Effects With Preexisting Neuromuscular Disorders
Patients with neuromuscular disorders may be at increased risk of clinically significant effects, including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see Warnings and Precautions). Monitor individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) when given botulinum toxin.

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*).

Don't Risk Your Patients' Saftey

Imported products from foreign and unauthorized sources are not FDA approved, may be counterfeit or compromised, and can pose potential health risks to your patients.

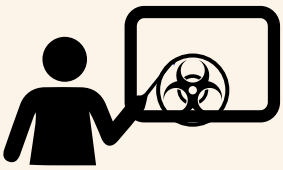
Peace of Mind for You—and Your Patients

The best way to avoid products of unknown origin is to verify that you are ordering authentic BOTOX® Cosmetic from Allergan Aesthetics or a distributor authorized by Allergan Aesthetics.
To view authorized suppliers, visit hcp.botoxcosmetic.com/home/authenticity.

MISBRANDED, NON–FDA-APPROVED OR ADULTERATED PRODUCT[2]:

- Medications purchased from foreign or unlicensed sources may be:

  - Misbranded
  - Adulterated
  - Counterfeit
  - Contaminated
  - Improperly stored and transported
  - Ineffective
  - Unsafe



EDUCATE PATIENTS ON THE DANGERS OF "FAUXTOX"

If a patient asks for a cheaper alternative to BOTOX® Cosmetic (onabotulinumtoxinA), let them know that injecting an unknown, foreign product could be harmful and that there
are other ways to save without compromising their results and safety.

DID YOU KNOW?

Allergan Aesthetics controls the manufacturing, production, and distribution of BOTOX® Cosmetic from start to finish.

Preexisting Conditions at the Injection Site
Use caution when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Dry Eye in Patients Treated With BOTOX® Cosmetic
There have been reports of dry eye associated with BOTOX® Cosmetic injection in or near the orbicularis oculi muscle. If symptoms of dry eye (eg, eye irritation, photophobia, or visual changes) persist, consider referring patients to an ophthalmologist.

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 a 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), which would also be considered 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.

Verify authenticity in 5 steps

Protect yourself by knowing and recognizing the characteristics of authentic Allergan Aesthetics product.

We're committed to doing whatever we can to help. Use the guide below to make sure the BOTOX® Cosmetic you use is the real thing. Together, we'll protect our patients and our industry.

1 ESTABLISHED NAME

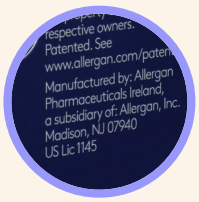
Ensure that the established name, onabotulinumtoxinA, appears on the product box and vial.

2 HOLOGRAM

Look for the Allergan hologram on each vial.

3 TAMPER SEAL

Check for the tamper-evident seal on the box to ensure that the product has not been tampered with.



4 LICENSE NUMBER

Check for US license #1145 on the carton and the vial label.

5 TRACK AND TRACE

Allergan Aesthetics is able to verify that each unit is authentic and approved for sale in the United States.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for glabellar lines were eyelid ptosis (3%), facial pain (1%), facial paresis (1%), and muscular weakness (1%).

The most frequently reported adverse reaction following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

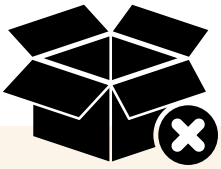
The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for forehead lines with glabellar lines were headache (9%), brow ptosis (2%), and eyelid ptosis (2%).

The safety profile of BOTOX® Cosmetic treatment of platysma bands is consistent with the known safety profile of BOTOX® Cosmetic for other indications.

DRUG INTERACTIONS

Coadministration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, 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® Cosmetic may potentiate systemic anticholinergic effects.

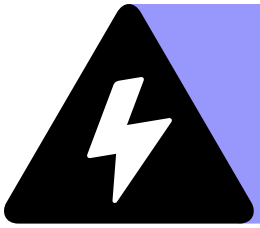
Please see additional Important Safety Information on following page.



PRODUCTS OF UNKNOWN ORIGIN—POTENTIAL SIGNS

- Significantly discounted BOTOX® Cosmetic may indicate counterfeit, stolen, expired, or illegally obtained product
- A supplier claims their product is "equivalent to BOTOX® Cosmetic (onabotulinumtoxinA)" or "approved in another country"
- Altered or unprofessional packaging and/or labeling that is not in English
- Botulinum toxin product not stored under the required conditions
  - Reconstituted and unopened vials of BOTOX® Cosmetic must be stored in a refrigerator 2°C to 8°C (36°F to 46°F). Reconstituted vials must be administered within 24 hours[3]

Report suspicious activity to the FDA Office of Criminal Investigations at www.fda.gov/oci and www.fda.gov/drugs/drug-safety-and-availability/drug-supply-chain-integrity.



COUNTERFEIT PRODUCT COMES WITH REAL CONSEQUENCES FOR BOTH PHYSICIANS AND PATIENTS.
DON'T RISK IT—PURCHASE ONLY FROM AUTHORIZED ALLERGAN AESTHETICS CHANNELS.

IMPORTANT SAFETY INFORMATION (continued)
DRUG INTERACTIONS (continued)
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® Cosmetic.

USE IN SPECIFIC POPULATIONS
There are no studies or adequate data from postmarketing surveillance on the developmental risk associated with use of BOTOX® Cosmetic in pregnant women. There are no data on the presence of BOTOX® Cosmetic in human or animal milk, the effects on the breastfed child, or the effects on milk production.

Please see BOTOX® Cosmetic full Prescribing Information including Boxed Warning and Medication Guide.

REFERENCES: 1. Bradshaw S. Cosmetic practitioners take huge risks purchasing and administering illegal botulinum toxin drug products. *J Drugs Dermatol.* 2017;16(9):936-938. **2.** US Food and Drug Administration. Counterfeit version of BOTOX® found in the United States. US Food and Drug Administration website. https://www.fda.gov/Drugs/DrugSafety/ucm443217.htm. Updated February 26, 2018. Accessed May 12, 2025. **3.** BOTOX® Cosmetic Prescribing Information, October 2024.

Allergan Aesthetics
an AbbVie company