

BOTOX® Cosmetic (onabotulinumtoxinA)

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

The recommended dosage and frequency of administration for BOTOX® Cosmetic should not be exceeded. Risks resulting from administration at higher dosages are not known.

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX® Cosmetic 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® Cosmetic cannot be compared to or 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) have been reported.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic 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.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of BOTOX® Cosmetic.

PRECAUTIONS

Caution should be used when BOTOX® Cosmetic treatment is used in patients who have an inflammatory skin problem at the injection site, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin, or the inability to substantially lessen glabellar lines by physically spreading them apart.

Information for Patients

Patients should be counseled that if loss of strength, muscle weakness, or impaired vision occur, they should avoid driving a car or engaging in other potentially hazardous activities.

Pregnancy

Administration of BOTOX® Cosmetic is not recommended during pregnancy. There are no adequate and well-controlled studies of BOTOX® Cosmetic in pregnant women.

Nursing Mothers

It is not known whether BOTOX® Cosmetic 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.

ADVERSE REACTIONS

General

The most serious adverse events reported after treatment with botulinum toxin include spontaneous reports of death, sometimes associated with anaphylaxis, dysphagia, pneumonia, and/or other significant debility.

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 pre-existing cardiovascular disease.

The most frequently reported adverse events following injection of BOTOX® Cosmetic include blepharoptosis and nausea.

Overdosage

Excessive doses of BOTOX® Cosmetic may be expected to produce neuromuscular weakness with a variety of symptoms. Respiratory support may be required where excessive doses cause paralysis of respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis.

In the event of suspected or actual overdosage, please contact your local or state health department to process a request for antitoxin through the Centers for Disease Control and Prevention (CDC). If you do not receive a response within 30 minutes, please contact the CDC directly at 1-770-488-7100.

Please see BOTOX® Cosmetic full [Prescribing Information](#) including [Medication Guide](#).



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