BOTOX® SAFETY INFORMATION

DISTANT SPREAD OF TOXIN EFFECT
BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms which may include generalized muscle weakness and fatigue, visual and speech difficulties, urinary incontinence, and breathing and swallowing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening.
The risk of symptoms is probably greatest in children treated for spasticity and in particular in the treatment of cervical dystonia, but symptoms can also occur in adults treated for spasticity, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

CONTRAINDICATIONS
BOTOX® 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
The potency Units of BOTOX® are specific to the preparation and are not interchangeable with other preparations of botulinum toxin products.
Serious and/or immediate hypersensitivity-allergy-anaphylaxis reactions have been reported.
Patients with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) may be at increased risk of side effects including severe dysphagia and respiratory compromise from typical doses of BOTOX®.
Patients with compromised respiratory status treated with BOTOX® for upper limb spasticity should be monitored closely.
Reduced blinking from BOTOX® injection of the orbicularis muscle for blepharospasm can lead to corneal ulceration, especially in patients with VII nerve disorders.
During the administration of BOTOX® for the treatment of strabismus, retrobulbar hemorrhages have occurred.

MOST FREQUENTLY REPORTED ADVERSE REACTIONS FOLLOWING INJECTION OF BOTOX®

- for upper limb spasticity include pain in extremity, muscle weakness, fatigue, nausea, and bronchitis.
- for cervical dystonia include dysphagia (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).
- for blepharospasm include ptosis (21%), superficial punctate keratitis (6%), and eye dryness (6%).
- for strabismus include ptosis (15.7%) and vertical deviation (16.9%).

- for severe primary axillary hyperhidrosis include injection site pain and hemorrhage, non-axillary sweating, infection, pharyngitis, flu syndrome, headache, fever, neck or back pain, pruritus, and anxiety.

RISK OF DEATH

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, and events involving the cardiovascular system, including arrhythmia and myocardial infarction, after treatment with botulinum toxin. 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.