



## Instructions for Use: Photo Files

### Step 1 View the Photo Files

- Double-click on the file(s) you downloaded—they should open automatically
  - If not, contact your IT professional or go to the software manufacturer's website to install the correct software on your computer

Software to Open Files	JPEG	PDF
Windows® Picture Viewer	•	
Adobe® Acrobat® Reader® <a href="http://get.adobe.com/reader/">http://get.adobe.com/reader/</a>	•	•
Mac OS® Preview	•	•

**NOTE:** If your software is not on these lists, please refer to your computer's user manual to check for software that will support these file formats.

### Step 2 Create Your Promotional Materials

- **Option 1 (preferred):** Provide these files to your graphic designer or webmaster for print or web implementation
- **Option 2:** To create your own designs, please refer to the chart below for standard layout programs and file import options

Compatible Software for Design	JPEG	PDF
Microsoft® Publisher 2010	•	
Microsoft® Office Word 2010	•	
Microsoft® Office PowerPoint® 2010	•	
CorelDRAW® X5	•	•
Adobe® Illustrator® CS5	•	•
Adobe® Photoshop® CS5	•	•
Adobe® InDesign® CS5	•	•
The Print Shop® 2.0	•	
QuarkXPress® 9	•	•

### Follow the Instructions Below When Using the Logo, Brand Name, or Branding Images

1. The Important Safety Information **must** be displayed whenever the BOTOX® Cosmetic (onabotulinum-toxinA) logo, brand name, branding images, or photo files appear. You may use the included PDF to copy and paste into your practice materials.
2. The Important Safety Information should not be changed in any way. It cannot be abbreviated or altered.
3. The full Product Information including Boxed Warning and Medication Guide should be given out any time a patient is treated with BOTOX® Cosmetic. These items should also accompany any material you distribute that contains the BOTOX® Cosmetic logo or brand name.

#### Indication

BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in patients 18 to 65 years of age.

#### IMPORTANT SAFETY INFORMATION, INCLUDING BOXED 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, blurred vision, 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 underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

Please see additional Important Safety Information on following page.

## **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.

#### **Human Albumin**

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

#### **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.

#### **Drug Interactions**

Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like nondepolarizing blockers, lincosamides, polymyxins, quinidine, magnesium sulfate, anticholinesterases, succinylcholine chloride) should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes 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.

#### **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.

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



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