

## Summary of Information About BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA)

### What is the Most Important Information I Should Know About BOTOX<sup>®</sup> Cosmetic?

**BOTOX<sup>®</sup> Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX<sup>®</sup> Cosmetic:**

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

There has not been a confirmed serious case of spread of toxin effect when BOTOX<sup>®</sup> Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines or both at the same time.

BOTOX<sup>®</sup> Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX<sup>®</sup> Cosmetic. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

**BOTOX<sup>®</sup> Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.**

### What is BOTOX<sup>®</sup> Cosmetic?

BOTOX<sup>®</sup> Cosmetic is prescription medicine a medical professional injects into muscles to temporarily improve the look of both moderate to severe crow's feet lines and frown lines between the eyebrows in adults.

### Who Should Not Use BOTOX<sup>®</sup> Cosmetic?

Do not use BOTOX<sup>®</sup> Cosmetic if you are: allergic to any of the ingredients in BOTOX<sup>®</sup> Cosmetic such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as *Myobloc<sup>®</sup>* (rimabotulinumtoxinB), *Dysport<sup>®</sup>* (abobotulinumtoxinA), or *Xeomin<sup>®</sup>* (incobotulinumtoxinA); or have a skin infection at the planned injection site.

### What Should I Tell My Doctor Before Treatment?

Tell your doctor about all your muscle or nerve conditions, such as amyotrophic lateral sclerosis (Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects.

Tell your doctor if you have or have had bleeding issues; plan to or have had surgery; have forehead muscle weakness such as trouble raising your eyebrows; drooping eyelids; or any changes to your face.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or plan to breast feed. It is not known if BOTOX<sup>®</sup> Cosmetic can harm your unborn baby or if BOTOX<sup>®</sup> Cosmetic passes into breast milk.

### What Are Common Side Effects?

The most common side effects include temporary injection site pain; weakening of adjacent facial muscles; drooping eyelids; swelling eyelids; and headache. Other side effects, while less common, have been reported including blurred vision, double vision and allergic reactions (itching, rash, red itchy welts, wheezing, asthma symptoms, dizziness or feeling faint).

These are not all of the possible side effects. Call your doctor for medical advice if you experience any side effects after treatment with BOTOX<sup>®</sup> Cosmetic.

### What Should I tell My Doctor About Medicines and Vitamins I Take?

Using BOTOX<sup>®</sup> Cosmetic with certain medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX<sup>®</sup> Cosmetic in the past.** Tell your doctor if you have received an injection with another botulinum toxin product in the last 4 months, such as *Myobloc<sup>®</sup>*, *Dysport<sup>®</sup>*, or *Xeomin<sup>®</sup>*. Be sure your doctor knows which product you received.

Tell your doctor about all prescription and over-the-counter medicines and supplements you take including: vitamins and herbal products; recent antibiotic injections; anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products; and blood thinners. Ask your doctor if you are not sure whether your medicine is listed above.

### To Learn More

If you would like more information, talk to your doctor and/or go to [BotoxCosmetic.com](http://BotoxCosmetic.com) for full Product Information.

You may report side effects to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Approved Uses

BOTOX<sup>®</sup> Cosmetic is a prescription medicine that is injected into muscles and used to temporarily improve the look of both moderate to severe crow's feet lines and frown lines between the eyebrows in adults.

## IMPORTANT SAFETY INFORMATION

**BOTOX<sup>®</sup> Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX<sup>®</sup> Cosmetic:**

- **Problems swallowing, speaking, or breathing**, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing

**BOTOX<sup>®</sup> Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.**

There has not been a confirmed serious case of spread of toxin effect when BOTOX<sup>®</sup> Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, or both at the same time.

BOTOX<sup>®</sup> Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX<sup>®</sup> Cosmetic. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

**Serious and/or immediate allergic reactions have been reported.** They include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

**Do not take BOTOX<sup>®</sup> Cosmetic if you:** are allergic to any of the ingredients in BOTOX<sup>®</sup> Cosmetic (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*<sup>®</sup> (rimabotulinumtoxinB), *Dysport*<sup>®</sup> (abobotulinumtoxinA), or *Xeomin*<sup>®</sup> (incobotulinumtoxinA); have a skin infection at the planned injection site.

**Tell your doctor about all your muscle or nerve conditions**, such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX<sup>®</sup> Cosmetic.

**Tell your doctor about all your medical conditions, including:** plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping

eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX<sup>®</sup> Cosmetic can harm your unborn baby); are breast-feeding or plan to (it is not known if BOTOX<sup>®</sup> Cosmetic passes into breast milk).

**Tell your doctor about all the medicines you take**, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX<sup>®</sup> Cosmetic with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX<sup>®</sup> Cosmetic in the past.**

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*<sup>®</sup>, *Dysport*<sup>®</sup>, or *Xeomin*<sup>®</sup> in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.

**Other side effects of BOTOX<sup>®</sup> Cosmetic include:** discomfort or pain at the injection site; headache; and eye problems: double vision, blurred vision, drooping eyelids, and swelling of your eyelids.

For more information refer to the Medication Guide or talk with your doctor.

To report a side effect, please call Allergan at 1-800-433-8871.

**[Please see accompanying BOTOX<sup>®</sup> Cosmetic full Product Information including Boxed Warning and Medication Guide.]**

**[Please see accompanying Summary of Information about BOTOX<sup>®</sup> Cosmetic.]**