

Summary of Information About BOTOX[®] Cosmetic (onabotulinumtoxinA)

What Is the Most Important Information I Should Know About BOTOX[®] Cosmetic?

BOTOX[®] 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[®] 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[®] Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, and/or forehead lines.

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

BOTOX[®] Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.

What is BOTOX[®] Cosmetic?

BOTOX[®] Cosmetic is a prescription medicine for adults that is injected into muscles and used for a short period of time (temporary) to improve the look of moderate to severe:

- frown lines between the eyebrows
- crow's feet lines
- forehead lines

Who Should Not Receive BOTOX[®] Cosmetic?

Do not receive BOTOX[®] Cosmetic if you are: allergic to any of the ingredients in BOTOX[®] Cosmetic such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as *Myobloc[®]* (rimabotulinumtoxinB), *Dysport[®]* (abobotulinumtoxinA), or *Xeomin[®]* (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 breastfeed. It is not known if BOTOX[®] Cosmetic can harm your unborn baby or if BOTOX[®] Cosmetic passes into breast milk.

What Are Common Side Effects?

Other side effects, while less common, have been reported including dry mouth; tiredness; neck pain; double vision, blurred vision, decreased eyesight, dry eyes; 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[®] Cosmetic.

What Should I Tell My Doctor About Medicines and Vitamins I Take?

Using BOTOX[®] 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[®] 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[®]*, *Dysport[®]*, or *Xeomin[®]*. 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 for full Product Information.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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