

Indication

BOTOX® Cosmetic is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary).

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

BOTOX® Cosmetic may cause serious side effects that can be life threatening. Call your doctor or 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 (dysphonia), trouble saying words clearly (dysarthria), 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.

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

Tell your doctor about all your muscle or nerve conditions, such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including severe dysphagia (difficulty swallowing) and respiratory compromise (difficulty breathing) from typical doses of BOTOX® Cosmetic.

Tell your doctor about all your medical conditions, including if you have: plans to have surgery; had surgery on your face; weakness of forehead muscles, such as trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® Cosmetic can harm your unborn baby); are breast-feeding or plan to breast-feed (it is not known if BOTOX® Cosmetic passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products.

BOTOX® Cosmetic may cause loss of strength or general muscle weakness, or vision problems.

If this happens, do not drive a car, operate machinery, or do other dangerous activities.

Other side effects of BOTOX® Cosmetic include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Full Product Information, including Medication Guide, has been provided to your doctor.