

FAQs about Botox® Cosmetic and Dysport® Wrinkle-Reducing Injections

What are Botox® Cosmetic and Dysport®?

Botox® Cosmetic and Dysport® are botulinum type A drugs approved by the U.S. FDA for cosmetic indications. These drugs are also approved for unrelated treatments, specifically the neuromuscular medical condition, cervical dystonia, that causes a severe muscle spasm of the neck.

How are Botox® Cosmetic and Dysport® used cosmetically?

The FDA has approved Botox® Cosmetic and Dysport® for use as a cosmetic injection to prevent or treat the formation of frown lines between the brows.

In addition, your physician may inject Botox® Cosmetic or Dysport® to treat similar cosmetic conditions. This may include injection to treat the muscle contractions that result in conditions such as crow's feet, visible lines at the temples or forehead, and bleed lines surrounding the lips.

Botox® is also approved as a treatment for axillary hyperhidrosis, excessive sweating of the underarm, and can be injected to treat excessive perspiration of the underarms, palms and soles of the feet.

Are Botox® Cosmetic and Dysport® interchangeable?

Botox® Cosmetic and Dysport® are not interchangeable; they are measured and diluted in differing doses and therefore equal amounts of Botox® Cosmetic and Dysport® do not produce identical outcomes. Both products must be prescribed by a physician.

Whether you are treated with Botox® Cosmetic or Dysport®, physicians recommend that you be injected with only one of these drugs in a given area during a single treatment session. In the event that your initial treatment does not produce the desired results, you may be re-injected with the same drug, to marginally increase your dosing and produce the desired effect.

What are the potential complications if I am injected with Botox® Cosmetic or Dysport®?

When injected for cosmetic purposes the potential risks most commonly reported include redness and mild bruising or swelling at the injection site. These are normal side effects of any injection and should only raise concern if symptoms persist beyond a few days of your injection. In very rare cases you may develop a droopy eyelid, a mild headache or mild flu-like symptoms.

Report any potential or perceived symptoms as described above immediately to the doctor who prescribed your injection. You will be examined and your physician will determine if any follow-up treatment is necessary. He or she may also report the specific complication or "adverse event" to the U.S. FDA Adverse Event Reporting System (AERS).

Since 1997, 21.9 million injections* of the neurotoxins Botox® Cosmetic and Dysport® have been performed by board-certified plastic surgeons, facial plastic surgeons, oculoplastic surgeons and dermatologists, with a consistent record of safe and successful outcomes.

Why do Botox® and Dysport® carry a "boxed" warning?

Botox® and Dysport® are also approved for treatment of specific medical disorders in addition to the cosmetic treatment of wrinkles. Myobloc® is the brand name of a third neurotoxin that is FDA approved for therapeutic or medical purposes; Myobloc® is not approved for cosmetic purposes.

The dosing to treat these medical conditions is many multiples higher than treating cosmetic indications, such as wrinkles. As with most drugs, significantly higher doses carry a higher potential for adverse outcomes. There have been reports in medical patients treated with these much higher doses of drug dispersion beyond the injection site causing symptoms ranging from unexpected muscle weakness to trouble speaking, trouble breathing, loss of bladder control or vision problems.

To better educate patients on the potential complications when treating specific neuromuscular conditions, the U.S. FDA has required a boxed warning on the label, and a REMS or Risk Evaluation and Mitigation Strategy for all neurotoxins. In April 2009, Dr. Ellis F. Unger, acting deputy director of the FDA's Office of Drug Evaluation stated specifically that none of the cases of adverse events reported that prompted the boxed warning are associated with the use of botulinum products in cosmetic or dermatologic procedures, such as treating furrows between the eyebrows.

For more FAQs and information on cosmetic injections and your safety and your beauty, visit www.injectablesafety.org.

* As compiled from the Cosmetic Surgery National Data Bank Statistics