

Frequently Asked Questions About the FDA's Action on Botulinum Toxin Products

1. What announcement did the U.S. Food and Drug Administration (FDA) make regarding botulinum toxin products?

The FDA announced on April 30, 2009, that a boxed warning will be added to the labeling of botulinum toxin products and a medication guide will be distributed to patients receiving these products for any use.

2. Why did the FDA add a boxed warning to botulinum toxin products?

The FDA added a boxed warning to botulinum toxin products because of the serious side effects that have occurred in both approved and unapproved uses where the botulinum toxin product has spread beyond the injection site causing symptoms of botulism, a rare, but serious disease affecting the nervous system. Symptoms can include difficulty breathing, difficulty swallowing, muscular weakness, drooping eyelids, constipation, aspiration pneumonia, speech disorder, facial drooping, double vision, or respiratory depression.

These serious side effects occurred primarily in children being treated for muscle spasms due to cerebral palsy, and in adults being treated for spasms or cervical dystonia.

3. Have any serious side effects been noted when using botulinum toxin products for dermatologic use?

The FDA reports that no serious side effects have been reported from the dermatologic use of botulinum toxin products when used as approved by the FDA.

4. What has the American Academy of Dermatology said about the FDA's actions?

The Academy's president, dermatologist David M. Pariser, MD, FAAD, released the following statement on behalf of the Academy:

"The health, safety and welfare of our patients being treated with botulinum toxin products are of paramount importance to dermatologists. While no serious side effects have been reported from the dermatologic use of botulinum toxin products, the FDA's actions emphasize the importance of selecting a qualified physician to administer these products for medical and cosmetic uses. The added precautions required by the FDA will provide patients with information to make the best decisions for their personal health. It also will help physicians ensure that patient safety is preserved."

5. What will the new medication guide tell patients receiving botulinum toxin products?

The medication guide for patients, their families, and caregivers will explain the risks of serious side effects due to product spreading beyond the injection site. The medication guide has not yet been developed and once it is available, patients will receive it when considering receiving botulinum toxin products. The guide would be provided to the patients by the individual who will be dispensing the botulinum toxin product.

The FDA will develop the patient medication guide as part of the development and implementation of a risk evaluation and mitigation strategy (REMS) that will ensure that the benefits of botulinum toxin products outweigh the risks. The REMS would include a communication plan for healthcare professionals to provide them with more information regarding the risk for the spread of botulinum toxin after injection, as well as information to explain that botulinum toxin products cannot be interchanged.

6. What are botulinum toxin products FDA-approved to treat?

Depending on the brand, botulinum toxin products are FDA-approved for the dermatologic treatment of frown lines between the eyebrows and severe underarm sweating (hyperhidrosis). They also are approved for treating crossed eyes, spasms of the eyelids and cervical dystonia (repetitive spasms of the neck muscles).

However, botulinum toxin products can be effectively used for "off-label" treatments in dermatology and other medical specialties.

7. Before receiving a treatment with botulinum toxin products, what questions should patients ask?

The Academy recommends that patients do their homework and consider a physician's training and credentials before they decide if botulinum toxin products are right for them.

- Is the treatment being performed by a physician experienced in this procedure?
- What results can be expected?
- How long is the recuperation period? Ask to see before and after photos of the physician's previous patients.
- What are the risks?
- Where is the procedure usually performed?
- What is the cost?

8. What has the FDA instructed healthcare professionals to be aware of in regards to the boxed warning?

As part of the REMS, the FDA has advised all healthcare professionals who use botulinum toxin products to:

- Understand that botulinum toxin products and their clinical doses are not interchangeable from one product to another.
- Be alert to and educate patients and caregivers about potential serious side effects due to spread of botulinum toxin products following injection.
- Understand that these serious side effects can appear as early as several hours and as late as several weeks after treatment.
- Advise patients to seek immediate medical attention if they develop any of these symptoms.

9. What is botulinum toxin?

Botulinum toxin type A and botulinum toxin type B are purified substances, derived from a bacteria, that block muscular nerve signals.

10. How do botulinum toxin products work?

When used for cosmetic dermatologic purposes, botulinum toxin products are injected in very small amounts into specific facial muscles blocking the muscle's impulse, weakening the muscle and diminishing the appearance of unwanted lines.

Other dermatologic uses include the treatment of hyperhidrosis, or excessive sweating. Botulinum toxin products are injected directly into the underarm skin to weaken the action of the skin's sweat glands which are responsible for excessive perspiration. Patients with excessive sweating on the palms of the hands or on the soles of the feet also can receive botulinum toxin product treatments in these locations, though this usage is considered off-label by the FDA.

11. Are there any side effects that occur normally following the use of botulinum toxin products?

Minimal, temporary and reversible side effects following the use of botulinum toxin products may include:

- Soreness or mild bruising around the injection site.
- A temporary headache after injections in the forehead area, especially after the first treatment.
- In rare instances, weakness of the neighboring muscles leading to a temporary droopy brow or eyelid.