

FDA Approves Botox to Treat Severe Underarm Sweating

FDA has approved Botulinum Toxin Type A (Botox) to treat severe underarm sweating known as "primary axillary hyperhidrosis" that cannot be managed by topical agents such as prescription antiperspirants. Botox has already been approved for several other purposes. Today's approval allows the product's manufacturer, Allergan, Inc., Irvine, Calif., to market Botulinum Toxin Type A for this new indication.

Botulinum Toxin Type A is a protein produced by the bacterium *Clostridium botulinum*. When used to treat primary axillary hyperhidrosis, small doses of an injectable form of the sterile purified botulinum toxin stop release of the chemical messenger acetylcholine, temporarily blocking the nerves in the underarm that stimulate sweating.

Botox was first approved in December 1989 to treat two eye muscle disorders (blepharospasm and strabismus). Since then it has been approved to treat cervical dystonia, a neurological movement disorder causing severe neck and shoulder muscle contractions. Most recently, in 2002, it was approved as Botox Cosmetic to temporarily improve the appearance of moderate to severe frown lines between the eyebrows.

In two placebo-controlled, multicenter, randomized, double-blind clinical trials involving over 600 adults, those who received Botox had significantly reduced underarm sweating as compared to the placebo group. In one study, four weeks after being injected, the percentage of people showing a 50% reduction in sweating was 91% in the group receiving Botox compared to 36% in the placebo group. In another study, the average duration of response following the first treatment was 170 days.

The most common adverse events following treatment (occurring in three to 10% of patients) included injection site pain and hemorrhage, sweating in other parts of the body, flu-like symptoms, headache, fever, itching, and anxiety.

Before being treated for primary axillary hyperhidrosis, patients should be evaluated for other potential causes of the problem, such as hyperthyroidism, to avoid symptomatic treatment of hyperhidrosis with

Botox without addressing a potentially serious underlying disease that requires other forms of treatment.

The safety and effectiveness of Botox for hyperhidrosis in body areas other than the axillae (armpits) has not been established.

Because Botox is a prescription drug, it must be used carefully under medical supervision for all the product's approved indications