A problem that may be managed

BOTOX®
Botulinum Toxin Type A

The original* and #1 selling toxin in the world†,1,2

*First licensed Botulinum Toxin Type A.
†Therapeutic and aesthetic use.[2] Based on market share in 16 countries in 2017.[1]

Allergan

Prescribing information
can be found on the back page

A problem that may

Severe axillary hyperhidrosis

- **Widely undiagnosed** and untreated[3]
- **Estimated to affect 1.4%** of the US population[3]
- Daily activities for **91.6%** of sufferers are adversely affected[3]
- Can result in **occupational, emotional, psychological, social and physical impairment**[3]
- **More than half** of sufferers have not discussed their condition with a Healthcare Professional[3]

You can help

BOTOX® Botulinum Toxin Type A

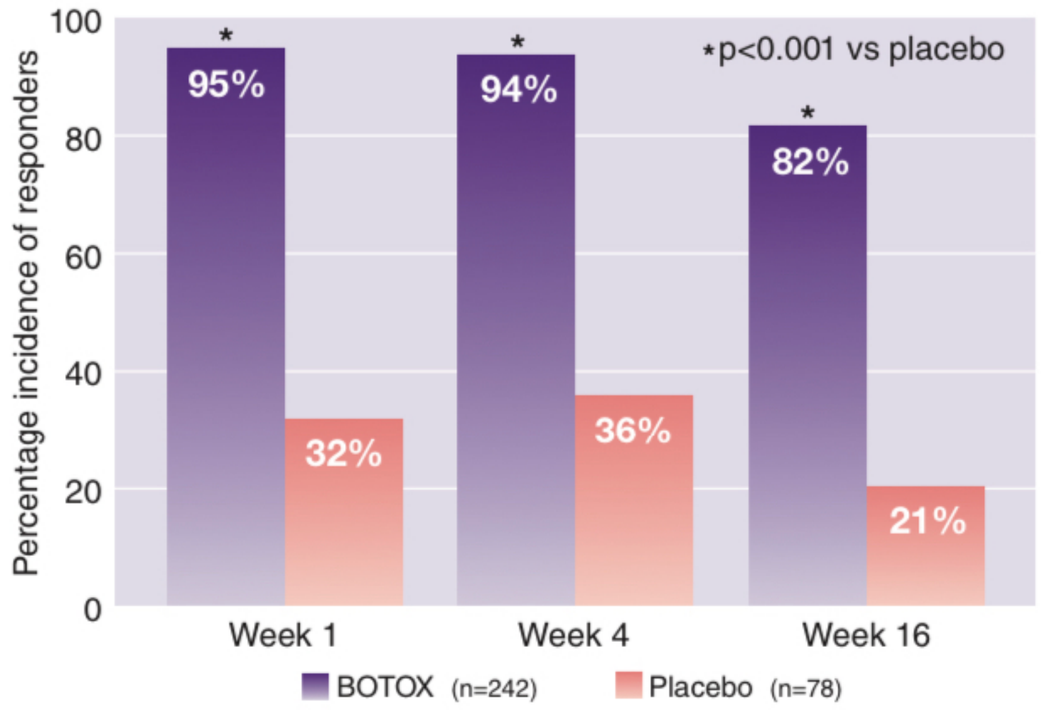
Lasting efficacy vs placebo [4] in severe axillary hyperhidrosis

High levels of response vs placebo [4]

defined as ≥ 50% reduction in axillary sweating from baseline

95% of patients responded to treatment in just one week

82% of patients were still responders after 16 weeks



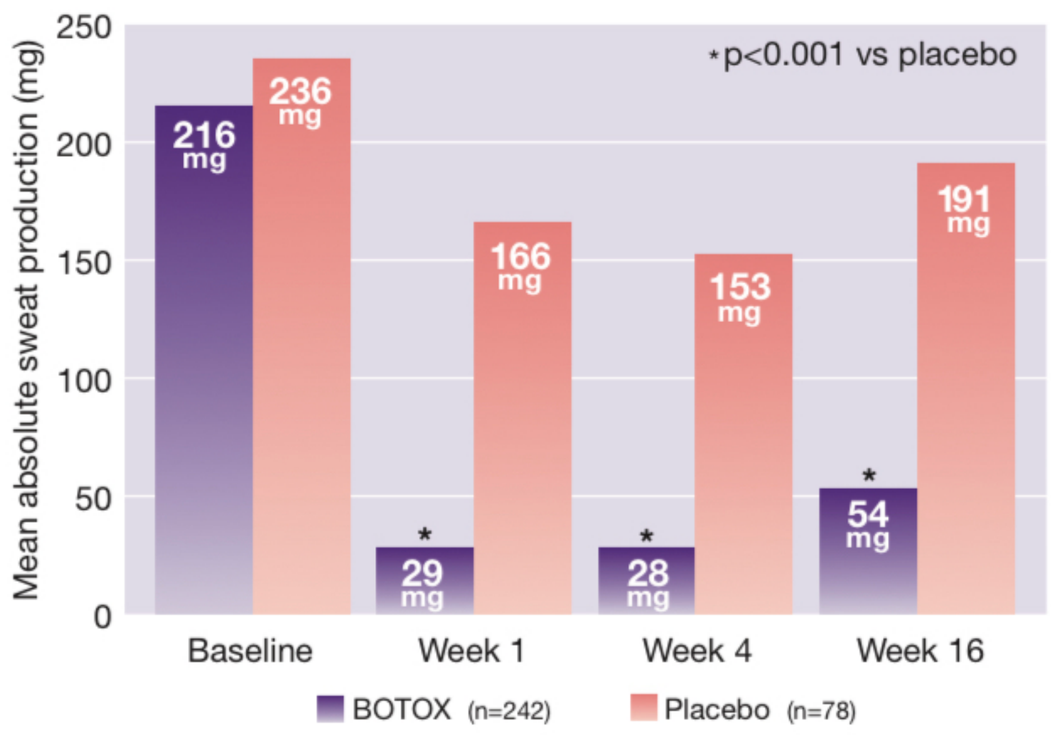
Adapted from Naumann & Lowe 2001

Significant reduction in sweating vs placebo [4]

86% reduction in absolute sweat production in just one week

87% reduction after four weeks

75% reduction even after 16 weeks



Adapted from Naumann & Lowe 2001

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High levels of satisfaction

vs placebo[5] in severe axillary hyperhidrosis

Patients express satisfaction vs placebo[5]

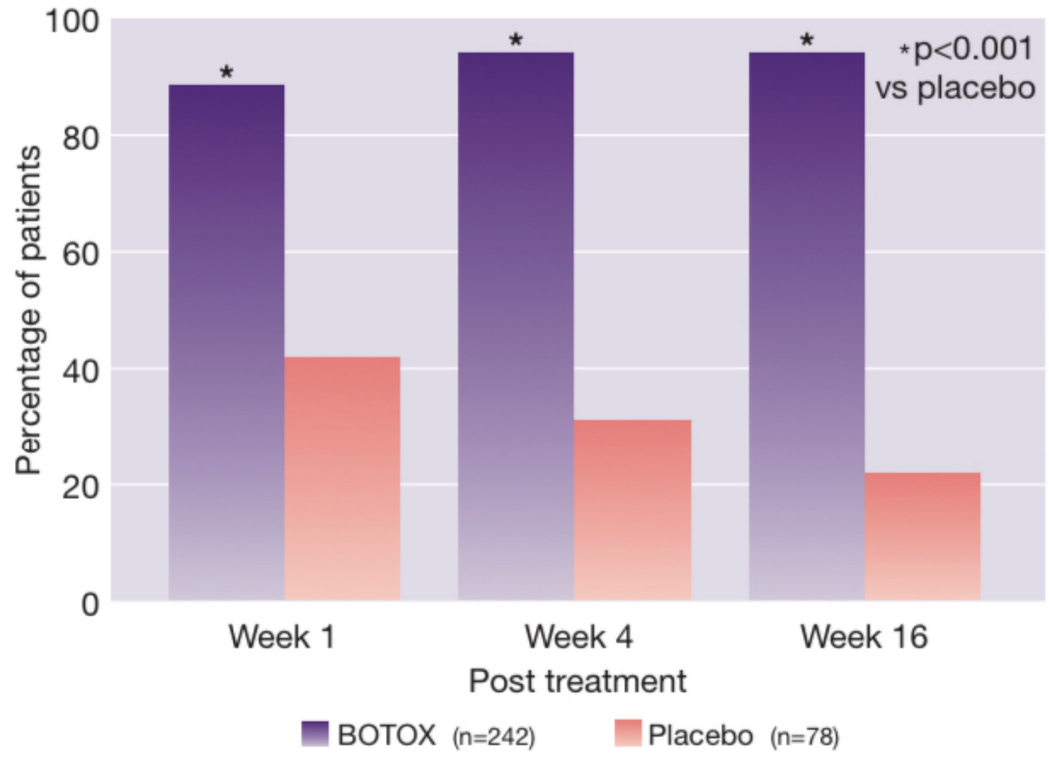
89% were satisfied after one week

93% were satisfied 15 weeks post treatment

Following treatment, patient satisfaction rates in their ability to perform work activities were significantly higher vs placebo ($p \leq 0.001$)[5]

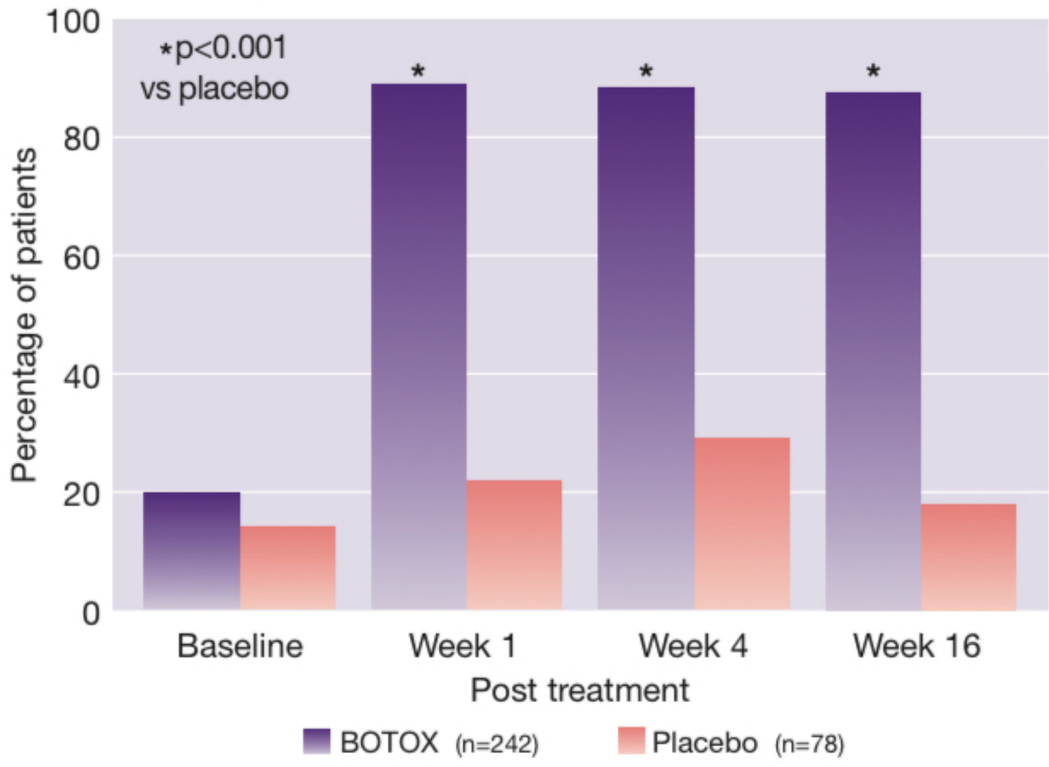
Generally adverse reactions occur within the first few days following injection and are generally transient. Non-axillary sweating was reported in 4.5% of patients whilst weakness of the arm was uncommon (0.7%), mild, transient and did not require treatment[6]

Percentage of patients much more, or somewhat more satisfied with BOTOX® than their previous treatment[5]



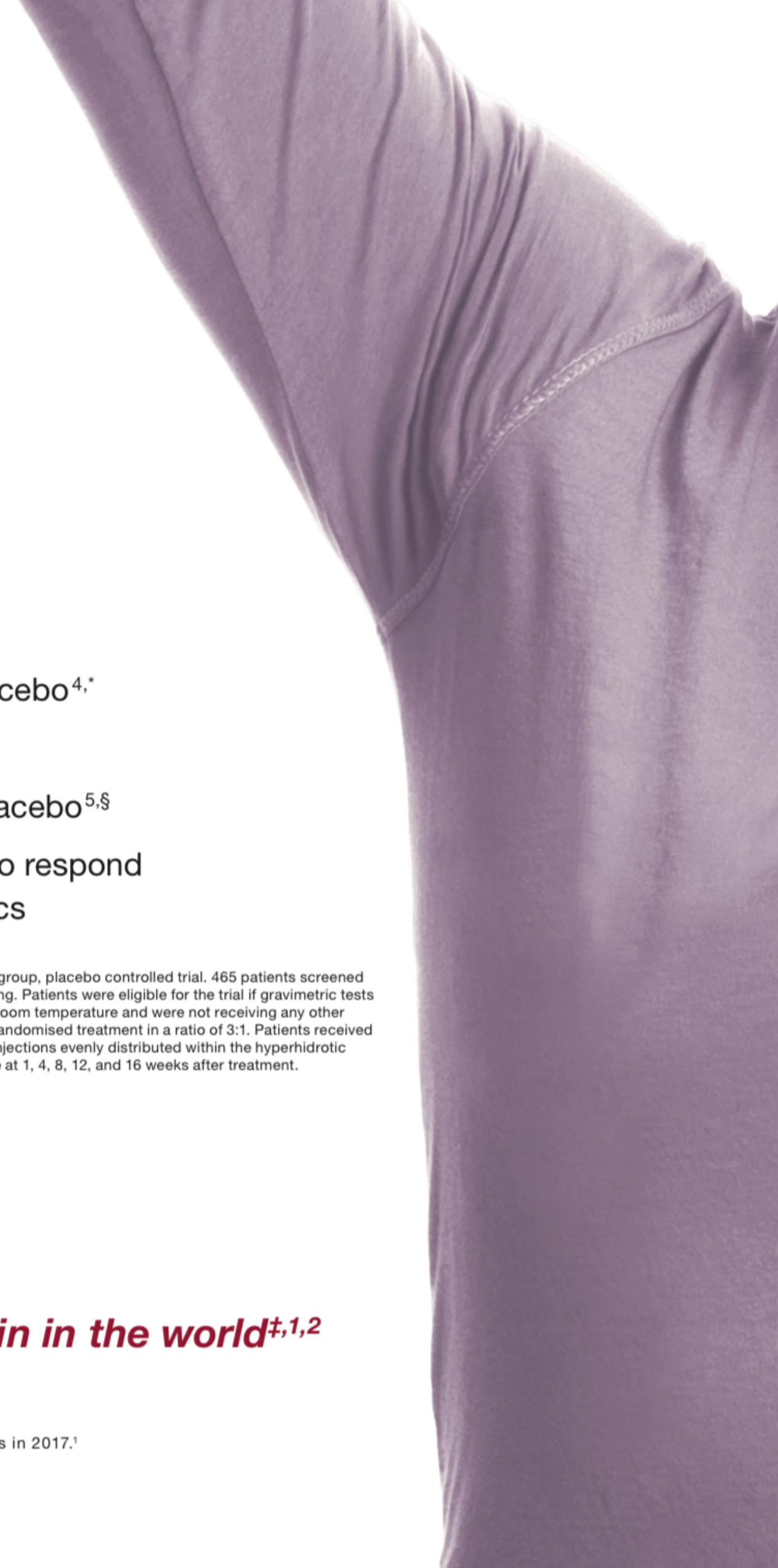
Adapted from Naumann, Hamm & Lowe 2002

Percentage of patients very satisfied or somewhat satisfied in their ability to perform current work activities[5]



Adapted from Naumann, Hamm & Lowe 2002

be managed



BOTOX® offers

- Effective control up to 16 weeks vs placebo[4,*]
- Improved quality of life vs placebo[5,§]
- High levels of patient satisfaction vs placebo[5,§]

When severe axillary hyperhidrosis fails to respond to topical antiperspirants and antihydrotics

§ Multicentre (Belgium, Gemany, Switzerland, United Kingdom), randomised, parallel group, placebo controlled trial. 465 patients screened for bilateral primary axillary hyperhidrosis that was sufficient to interfere with daily living. Patients were eligible for the trial if gravimetric tests showed that they produced >50 mg sweat per axilla over five minutes while at rest at room temperature and were not receiving any other treatment for hyperhidrosis. 320 patients met the criteria, 307 completed the study. Randomised treatment in a ratio of 3:1. Patients received either botulinum toxin type A (Botox) 50 U per axilla or placebo by 10-15 intradermal injections evenly distributed within the hyperhidrotic area of each axilla, defined by Minor's iodine starch test. Follow up assessments were at 1, 4, 8, 12, and 16 weeks after treatment.

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- The world's most studied botulinum toxin[7]
- Effective and lasting results vs placebo[4]
- Generally well tolerated[6]
- High levels of patient satisfaction vs placebo[5]
- An additional service for your clinic

BOTOX® – Primary hyperhidrosis of the axillae - Abbreviated Prescribing Information
Presentation: Botulinum toxin type A (from Clostridium botulinum), 50, 100 & 200 Allergan Units/vial. **Indications:** The management of severe hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirants or antihidrotics. **Dosage and Administration:** See Summary of Product Characteristics for full information. Botulinum toxin Units are not interchangeable from one product to another. BOTOX must only be reconstituted with sterile sodium chloride 9 mg/ml (0.9%) solution for injection. Single use only; unused solution to be discarded. If different vial sizes are being used as part of one injection procedure, care should be taken to use the correct amount of diluent when reconstituting a particular number of units per 0.1 ml. The amount of diluent varies between BOTOX 50, 100 and 200 Allergan Units. Each syringe should be labelled accordingly. Refer to specific guidelines for each indication below. In the event of treatment failure or diminished effect following repeat injections alternative treatment methods should be employed. *Primary hyperhidrosis of the axillae:* 50 Units/2 mL (0.1-0.2 ml) using a 30 gauge needle is injected intradermally to each axilla, evenly distributed in multiple sites approximately 1-2 cm apart. Doses other than 50 Units per axilla cannot be recommended. **Contraindications:** Known hypersensitivity to any constituent. Presence of infection at proposed injection site(s). **Warnings/Precautions:** Use not recommended in women who are pregnant, breast-feeding and/or women of childbearing potential not using contraception. The recommended dosages and frequencies of administration of BOTOX should not be exceeded due to the potential for overdose, exaggerated muscle weakness, distant spread of toxin and the formation of neutralizing antibodies. Initial dosing in treatment naive patients should begin with the lowest recommended dose for the specific indication. Prescribers and patients should be aware that side effects can occur despite previous injections being well tolerated thus exercise caution on the occasion of each administration. There are reports of side effects related to spread of toxin distant from injection site, sometimes resulting in death. The risk of symptoms is probably greatest in patients who have underlying conditions and comorbidities, including children and adults treated for spasticity, and are treated with high doses. Elderly and debilitated patients should be treated with caution. Dysphagia has also been reported following injection to sites other than the cervical musculature. BOTOX should only be used with extreme caution and under close supervision in patients with subclinical or clinical evidence of defective neuromuscular transmission and in patients with underlying neurological disorders. Caution in patients with underlying neurological disorder and history of dysphagia and aspiration. Patients should seek medical help if swallowing, speech or respiratory disorders arise. Previously sedentary patients should resume activities gradually. Relevant anatomy and changes due to prior surgical procedures must be understood prior to administration and injection into vulnerable anatomic structures must be avoided. Pneumothorax associated with injection procedure has been reported. Caution is warranted when injecting in proximity to the lung, particularly the apices or other vulnerable structures. Serious adverse events including fatal outcomes have been reported in patients who had received off-label injections directly into salivary glands, the oro-lingual-pharyngeal region, oesophagus and stomach. If serious and/or immediate hypersensitivity reactions occur (in rare cases), injection of toxin should be discontinued and appropriate medical therapy, such as epinephrine, immediately instituted. Procedure related injury could occur. Caution in the presence of inflammation at injection site(s) or when excessive weakness/atrophy is present in target muscle. Reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. New onset or recurrent seizure occurred rarely in predisposed patients, however relationship to botulinum toxin has not been established. Clinical fluctuations may occur during repeated use. Too frequent or excessive dosing can lead to antibody formation and treatment resistance. May cause asthenia, muscle weakness, somnolence, dizziness and visual disturbance which could affect driving and operation of machinery. *Paediatric use:* The safety and efficacy of BOTOX in indications other than those described for the paediatric population of the Summary of Product Characteristics, have not been established. BOTOX must be used for one single patient treatment only during a single session. Dispose unused product. Not recommended in individuals under 18 years. Limited phase 3 clinical data in patients older than 65 years. Take care not to inject in a blood vessel when injecting in the vertical lines between the eyebrows seen at maximum frown (also known as Glabellar Lines) or in the lateral canthal lines seen at maximum smile (also known as Crow's Feet Lines). There is a risk of eyelid ptosis following treatment. Refer to Summary of Product Characteristics for steps on how to minimize this risk. *Primary hyperhidrosis of the axillae:* Potential causes of secondary hyperhidrosis (e.g. hyperthyroidism, phaeochromocytoma) must be excluded prior to treatment (medical history and physical examination, along with specific additional investigations as required, should be performed). **Interactions:** Theoretically, effect may be potentiated by aminoglycoside antibiotics or other drugs that interfere with neuromuscular transmission (e.g. neuromuscular blocking agents). **Adverse Effects:** See Summary of Product Characteristics for full information on side effects, including details of uncommon, rare and very rare events. Adverse events usually occur within the first few days following injection and are transient, but may persist for several months or, rarely, longer. Local muscle weakness represents the expected pharmacological action. Localised pain, tenderness and/or bruising may be associated with the injection. Fever and flu syndrome have been reported. *Frequency:* Defined as Very Common (≥ 1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very Rare (<1/10,000). ***Primary hyperhidrosis of the axillae:*** Nervous system disorders - (*Common*: Headache and paraesthesia). Vascular disorders - (*Common*: Hot flushes). Skin and subcutaneous tissue disorders - (*Common*: Hyperhidrosis (non-axillary sweating) skin odour abnormal, pruritus, subcutaneous nodule and alopecia). Musculoskeletal and connective tissue disorders - (*Common*: Pain in extremity. General disorders and administration site conditions - (*Common*: Injection site pain) Please refer to the Summary of Product Characteristics for further information including adverse events that have been reported since the drug has been marketed. **Basic NHS Price:** 50 Units: £77.50, 100 Units: £138.20, 200 Units £276.40 **Marketing Authorisation Number:** 50 Units: 426/0118, 100 Units: 426/0074, 200 Units 426/0119. **Marketing Authorisation Holder:** Allergan Ltd, Marlow International, The Parkway, Marlow, Bucks, SL7 1YL, UK. **Legal Category:** POM. **Date of preparation:** April 2014.

Further information is available from: Allergan Limited, Marlow International, The Parkway, Marlow, Bucks SL7 1YL

Adverse events should be reported. Reporting forms and information can be found at **www.yellowcard.mhra.gov.uk**
Adverse events should also be reported to Allergan Ltd. **UK_Medinfo@allergan.com** or **01628 494026.**

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References:
1. Allergan. Data on file INT/0827/2017 September 2017. **2.** Allergan. Data on file. INT/0423/2016(1). **3.** Strutton DR *et al. J Am Acad Dermatol*, 2004;51:241-248. **4.** Naumann MK and Lowe NJ. *BMJ*, 2001; 323:596-599. **5.** Naumann MK, Hamm H, Lowe NJ. *Brit J Dermatol*, 2002;147:1-9. **6.** BOTOX® Summary of Product Characteristics. **7.** Allergan. Data on file. INT/0721/2017. About Botox®. September 2017.

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