

Informed Consent for Botox Therapeutic®

Patient Name / Label

Hyperhidrosis (Excessive Sweating)

Primary hyperhidrosis is a disorder that makes you sweat more than you need to and the cause is often not known. Other factors such as diabetes, menopause, nerve damage and some medications can also cause excessive sweating, called secondary hyperhidrosis.

This **Informed Consent** sheet relates to treatment of primary hyperhidrosis with Botox Therapeutic® for the underarms and/or hands only. This specific treatment is not covered by the Medical Services Plan.

Therapeutic treatment for *each* underarm is typically 50 units, and for each hand, 50-100 units. The cost for this medical procedure is \$8.50/unit + GST.

Alternative treatments (not provided at this clinic) include, but are not limited to: topical treatments (e.g., aluminum chloride hexahydrate), iontophoresis (low-intensity electric current to affected areas), or surgery.

Treatment success with Botox® for the underarms has shown that 95% of patients experience an average reduction of 83% in one week¹, with effects lasting an average of 7 months. As the patient, I have read the following and agree/understand each point:

- I am over the age of 18 and I have not had any Botox® within the past 12 weeks (please discuss with the doctor if you have).
- I am not pregnant and there is no chance that I could be pregnant at this time. I am not breast-feeding.
- I am not aware of any personal medical history of hypersensitivity or allergic reactions to Botox®.
- I do not have any active skin infections and generally feel well.
- I do not take blood thinners (e.g., warfarin, Apixaban/Eliquis, Rivaroxaban/Xarelto, Pradaxa/Dabigatran) or antiplatelet drugs (e.g., Plavix/Clopidogrel, Brilinta/Ticagrelor). Please notify the doctor if you take regular "baby aspirin" (ASA 81mg) or regular anti-inflammatory medications for pain (e.g., Advil, Aspirin, Celebrex, Motrin, Aleve, etc...).
- I do not have a known bleeding disorder. I do not have a neuromuscular condition (e.g., Myasthenia Gravis, Cerebral Palsy, ALS, previous Polio infection, Lambert-Eaton syndrome, etc.).
- I am aware this product contains human serum albumin which is a derivative of human blood (also important to know if you are a Jehovah's Witness).
- I am aware of the more common, temporary, side effects of Botox® injection(s), including:
 - Inflammation and/or bruising and/or localized pain around the injection site(s)
 - Swelling/edema, bleeding, tenderness, paresthesias ("pins/needles")
 - Compensatory sweating in other parts of the body
- I am aware of very rare, but potentially serious side effects of Botox® treatment, not limited to:
 - Distant spread of botulinum toxin resulting in secondary problems such as swallowing or speech disorders; muscle weakness; respiratory failure or complications; cardiovascular events; immunogenic/hypersensitive reactions (e.g., anaphylaxis), neurological conditions (e.g., Creutzfeldt-Jakob Disease), and other skin reaction(s).

Patient Signature

Date

Additional Safety Information from Allergan:

Safety Information³

BOTOX[®] is indicated for primary hyperhidrosis of the axillae for the treatment of hyperhidrosis of the axilla in patients 18 years of age or older.

Serious Warnings and Precautions

- The term “Allergan unit” upon which dosing is based is a specific measurement of toxin activity that is unique to Allergan’s formulation of botulinum toxin type A. Therefore, the “Allergan units” used to describe BOTOX[®] activity are different from those used to describe that of other botulinum toxin preparations and the units representing BOTOX[®] activity are not interchangeable with other products.
- BOTOX[®] should only be given by physicians with the appropriate qualifications and experience in the treatment and the use of required equipment.
- Follow the recommended dosage and frequency of administration for BOTOX[®].
- **DISTANT SPREAD OF TOXIN EFFECT:** The effects of BOTOX[®] and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

BOTOX[®] is onabotulinumtoxinA, a sterile, purified form of botulinum toxin type A.

Do not use BOTOX[®] if:

- you are allergic or sensitive to any of the ingredients
- you have an infection in the muscles where it would normally be injected
- you have any muscle disorders in other parts of your body, including myasthenia gravis, Eaton Lambert Syndrome or amyotrophic lateral sclerosis

Before you receive BOTOX[®], talk to your healthcare professional if:

- you have an infection at a proposed injection site
- you are scheduled to have surgery using a general anaesthetic
- you are taking or are likely to take antibiotics, especially aminoglycoside antibiotics
- you are pregnant or become pregnant or are nursing while taking this drug

Tell your doctor if you are taking other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

Pain, tenderness and/or bruising at the site of injection. Increase in sweating in other areas of the body and headaches. Malaise (generally feeling unwell), lasting up to six weeks after injection with BOTOX[®]. Weakness and rarely, changes in the way the heart beats, chest pain, skin rash and allergic reaction (symptoms: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin); anaphylaxis; cardiovascular events; seizures; dysphagia; and respiratory compromise. These are not all the possible side effects you may feel when taking BOTOX[®]. If you experience any side effects not listed here, contact your healthcare professional.

Consult the BOTOX[®] Product Monograph at <https://allergan-web-cdn-prod.azureedge.net/allergancanadaspecialty/allergancanadaspecialty/media/actavis-canada-specialty/en/products/pms/9060x-2018-10-16-en-botox.pdf> for complete safety information.

For more information about hyperhidrosis and how to manage your symptoms, go to sweatless.ca



1. Naumann MK, Lowe NJ. Botulinum toxin type A in the treatment of bilateral primary axillary hyperhidrosis: randomized, parallel-group, double blind, placebo-controlled trial. *British Medical Journal* 2001;323:1-4.