

Botulinum Toxin- Informed Consent Hyperhidrosis

Botox® injections are a new treatment option for severe primary axillary hyperhidrosis that has failed to improve with prescription antiperspirants. It prevents sweating in the specific area where it is injected.

Its efficacy in areas such as the arms, scalp, feet and face has not been established because, according to the director of human medicines at the Irish medicines Board, “as there are no muscles in the armpits there is less risk, but in other area such as the hands, there is a risk of muscle damage as the muscles and sweat glands lie side by side”.

Generally, botulinum injections are safe, but as is common with almost all drugs, side effects are likely to occur.

Common side effects, associated with the injection include;

- Pain or bruising at injection sites
- Inflammation of localized sites, redness, rashes
- Bleeding at injection site
- Bruising
- Numbness or itching of the area following injection.

These are minor side effects that could clear out spontaneously within, hours or a few days. However, they could last longer.

Serious side effects are extremely rare (3-10%). They occur when the injection affects the whole body and could occur hours, days, or weeks after the injections.

Rare but serious side effects include;

- Muscle weakness in the entire body
- Fatigue
- Infection
- Pharyngitis
- Flu-like symptoms
- Headache
- Dry mouth
- Fever
- Anxiety
- Neck or back pain
- Certain reactions to the injection could indicate allergy. Allergic reactions associated with Botulinum toxin include; wheezing, asthma, red welts, itching, dizziness and fainting. It is advisable to seek medical attention if any allergic reaction occurs.
- For treatment of facial hyperhidrosis, patients might experience teary eyes, droopy eyelids and/or eye dryness.

Adverse reactions are most likely to occur within the first week of treatment. They are mostly temporary, although some last longer than others.

Patients can resume normal activities immediately after Botox® injections. It might take two or three days before the patient stops sweating, and two weeks for total dryness. However, Botox® injections are a temporary fix, which can only last for four to fourteen months, for armpit treatment. For hands and feet, treatment may not last that long, as patients might need to repeat treatment in six months.

Material information provided:

I understand that whilst I have been advised as to a probable result, this should not be interpreted as a guarantee.

Alternative treatments I have been advised I may consider:

I confirm that the medical health history form has been completed truthfully and I am fully aware that withholding medical information may be detrimental to the safe and optimal outcome of any treatment that the practitioner agrees to undertake.

If there are any changes in my medical history, I must inform the practitioner.

I confirm the procedure has been explained comprehensively and that the possible risks and side effects associated with the treatment have been fully discussed and understood. I understand that though complications are uncommon, they do sometimes occur. It is possible that side effects not described may occur and indeed that a complication not previously reported or experienced may occur for the first time.

I confirm that I understand this is an elective non-surgical cosmetic procedure. I have been advised that there are alternatives to this procedure available, including the acceptance of my present condition.

I have had the opportunity to have any questions answered and the time to process and consider the information provided before making a decision to proceed with the agreed treatment plan.

I confirm that I have been provided with verbal and written information about this treatment which includes aftercare and follow up advice.

I agree to follow the aftercare advice and understand this reduces risk of adverse reactions and helps ensure optimum results.

I understand information about me will be confidential and access to it restricted in accordance with the Data Protection Act. Pre and post treatment photographs may be taken as part of my treatment record and kept in my personal medical file. Any such photographs will not be used without my consent for any other purpose.

I understand if I suffer any adverse reactions that are not expected, or concern me, I must contact the clinic. An appointment will be made for me to be seen. The clinic cannot take responsibility for

complications or results that have not been reported, assessed, documented and managed in a timely fashion.

The main reason for this treatment is-
For physical benefit, personal & psychological reasons

Patients Signature _____ Date _____

Print Name _____

Practitioners Signature _____ Date _____

What is Hyperhidrosis?

It seems natural for certain people to sweat profusely afterwards the sweat cools the body. Even in overactive people, the body adjusts to hyperactivity and disposes of the sweat. But when sweating becomes extreme, embarrassing, irritating and constant, it becomes a huge cause of concern.

This could affect an individual's life, self-esteem, confidence, career, relationship and output. Extreme and excessive sweating is classified under a medical term called "**hyperhidrosis**".

'Hyperhidrosis affects approximately 1-5% of the Irish population, and it is a problem that affects their lives both professionally and socially on day-to-day bases.'

What causes Hyperhidrosis?

Hyperhidrosis is categorised into two, based on their causes, to enable medical practitioners and understand their cause and consider treatment options. Hence we have; Primary Focal and Secondary Generalized Hyperhidrosis.

Focal hyperhidrosis occurs in localised areas such as face, armpit, scalp, groin and hands. This is the most common form of hyperhidrosis. On the other hand, Secondary hyperhidrosis is very rare and is associated with pre-existing conditions such as thyroid disease.

Generally, secondary hyperhidrosis is tackled by treating the underlying disease before other possible courses of actions are taken.

The cause of primary hyperhidrosis is not known.

What Treatments are Available?

Treatments for hyperhidrosis highly depend on the location of effect, i.e. face, hand armpit, groin or feet. Most antiperspirants can be gotten over the counter from pharmacies, with or without prescription, especially for palmar and facial hyperhidrosis.

For hand and armpit hyperhidrosis, also known as axillary hyperhidrosis, Driclor and Anhydrol forte have proven effective, according to an Irish GP, Dr John O'Keefe. However, the most effective method of axillary hyperhidrosis treatment is the administration of Botulinum Toxin injection.

However, Botox® is not generally used for treating hands, feet or facial areas. Botox works in two ways and can paralyse either a sweat gland or a muscle.

How Does Botox ® work?

Botulinum toxin (Type A) is a nerve toxin that temporarily paralyzes the nerve muscles and is mostly used for cosmetic treatment of wrinkles. However, it has proven its efficacy in the treatment of axillary hyperhidrosis. Due to its high success rate, the Irish Medicines Board granted a license to the use of Botox® for treating armpit hyperhidrosis.

The director of human medicines at the Irish Medicines Board, Dr Joan Gilvarry, explains: "The licence for botox was amended in 2003 to include the treatment of persistent severe primary hyperhidrosis of the axillae, which interferes with the activities of daily living and is resistant to topical treatment."

Botox® is a natural, purified protein that on administration is able to inhibit the activities of the chemical responsible for 'activating' excessive sweating. By inhibiting this chemical, excessive sweating can be suppressed for a period of four to fourteen months.

A small amount of Botox is injected with a very fine needle into roughly 25 to 20 spots in each armpit. This may produce up to 14 months of relief from sweating. The injections are uncomfortable, but use of a very small injection needle makes them tolerable.

Botox® is an alternative treatment often fallen back to when antiperspirants and other forms of treatment and therapy fail to be effective.

Am I suitable for treatment with Botox ®?

If a patient is suffering from hyperhidrosis and he/she has failed to respond to other forms of treatment, and the GP has verified from the patient's history that all efforts have proved abortive, such a patient is definitely suitable for botulinum injections.

A nurse would confirm a patient's eligibility from his/her record.

However, certain conditions could render a patient unsuitable for Botox®. They include,

- Having ALS (Lou_Gehrig's disease), myasthenia_gravis, Lambert-Eaton_syndrome or another disease that affects your muscles or nerves
- Being on medications such as certain vitamins, supplements and certain antibiotics.
 - These can be confirmed by the GP.
- Pregnancy and lactation.
- Skin infection in the injection area.
- Allergy to any ingredient in Botox® or the injection itself.
- Breathing problems such as asthma.

What does the treatment involve?

The nurse first identifies the most active glands in the affected area. This involves applying iodine solution to the area for treatment, then it is dusted with starch powder. This turns the area deep blue/black. A surgical pen is used to mark the area and cleaned before injecting the toxin.

Spacing of injections around affected areas is approximately 2cm. Tiny needles are used to minimize pain. Also, anaesthetic creams are applied.

Be Prepared

- Underarms are shaved, and use of antiperspirants is prohibited from 24 hours before injections.
- Aspirin, Vitamin E, non-steroidal medication, ginkgo biloba and St. John's Wort medication are terminated 24 hours before treatment as they could encourage bruising and bleeding.
- If the aspirin is being taken for a pre-existing condition, the GP must be informed in order for other drugs to control bleeding to be administered.
- Loose, dark and preferably old clothing should be worn for the appointment to avoid permanent stains from iodine or bleeding.

After Treatment

There is most likely to be a sore feeling on the treatment area. It is basically normal. Localised aches, fatigue and heaviness of area is mostly experienced by patients but these generally disappear after three days.

Recovery is a gradual process and can be judged within 2-3 weeks. Records of improvement are taken to prove efficacy of treatment and if need be, to modify treatment plan. In some cases, additional treatment is advised for optimum results.

Proper hygiene must be maintained, especially at treatment area. Patients are free to apply antiperspirants, as soon as the area has recovered, usually within 4-12 hours.

Extremely hot conditions and rigorous exercises should be avoided until 3 days after treatment. If any unexpected/unpleasant side effect is noticed, or symptoms of concern erupt, the clinic must be immediately alerted.

The treatment might not completely stop the sweating, but excessive sweating is guaranteed to greatly reduce. Treatment results are expected to last approximately 4-14 months. For some individuals this may be shorter, or even longer.

Once the Botox® wears off, the condition returns to its previous state, there is no permanent effect on the patient's condition, either for the better, or for the worse.

If you have any further questions, before, during or after the treatment, do not hesitate to ask the GP.