

Wrinkle Relaxation Information Sheet

This material is provided to help you make an informed choice regarding botulinum toxin treatment but does not replace discussions before going ahead with the procedure. You are encouraged to ask questions about the diagnosis, alternatives, procedure, fees, risks, benefits, descriptions, medical terms or language in this form.

What is Botulinum Toxin?

Botulinum toxin is a naturally occurring protein produced by the bacterium *clostridium botulinum*. In a purified form botulinum toxin is a very safe, effective treatment not only used in cosmetic clinics, but also for a number of medical conditions, including migraine and excessive sweating.

Background information: Botulinum toxin treatment has been performed for more than 20 years. It is used for cosmetic purposes, but also in blepharospasm (spasm of eyelid), strabismus (crossed eye), cervical dystonia (sustained muscle contraction of neck), chronic migraine, axillary hyperhidrosis (excess underarm sweating), and upper motor neurone syndrome.

How does it Work?

The toxin blocks the transition of chemical messages from the nerve to the muscle so that the muscle stays in a resting state for a period of 8 to 12 weeks on average. The result of relaxation of the muscle is improvement of the lines or wrinkles formed by action of that particular muscle.

This may be only a partial reduction in movement, allowing some remaining movement or a full block in which case there is very little remaining muscular movement in the area – this very much depends on the amount administered and location of product placement – treatment may be tailored to suit your individual requirements. Your expected treatment outcomes and whether they can be achieved will be discussed at the time of consultation.

Used to Treat



The aim of the treatment is to significantly reduce the movement of the muscles causing expression lines (dynamic lines) specifically the frown and crow's feet. Horizontal lines on the forehead may also be treated.

Successful treatment may not cause the expression lines themselves to disappear completely. It may not "completely freeze" the expression, particularly if extreme effort is exerted to make an expression. Even if you had previously had treatment with botulinum toxin which has completely "frozen" your expression, this may not be possible due to age changes, nor desirable.

Botulinum toxin is not suitable for lines present without expression (static lines) such as the nose to mouth lines or those *beneath* the eye. Dr Vaughan can advise you on alternative treatments for these areas if you wish.

Advanced and off-label indications include; horizontal brow lines, vertical lip lines, chin "poppling" when speaking, muscles on the lower face and neck, lifting the mouth corners, improve the jaw line and the appearance of the neck. The "chewing muscle" (masseter) may also be treated to soften a square jaw or to prevent teeth grinding or jaw clenching at night.

Please note that when we treat the forehead we unfortunately cannot treat lines 1-2cm above the eyebrows as this carries a high risk of unwanted drooping.

How Long will it Last?

Results can last 2-6 months, although 3-4 months is more common. Movement will begin recovering from 6-8 weeks. Frequent treatment at intervals of less than 3 months is not recommended. Repeating treatment when movement recovers will deliver optimum results over time due to the degree of muscle atrophy. Frequency of treatments may be reduced according to the quality of your skin and your response to treatment. Should you choose not to maintain the results and not have further treatment, your muscles and skin will return to their pre-treatment state.

Before Treatment

The pre operative consultation provides an explanation of botulinum toxin treatment, benefits, risks, options and determines your suitability.



It is important you tell your Dr Vaughan about any medicines or dietary supplements you are taking, some medicines can adversely affect the way the toxin works or increase your risk of bruising.

If you are taking supplements such as Vitamin A, C or E, Gingko Biloba, Garlic, fish oils, St. Johns Wort or some pain killing medicines such as aspirin or ibuprofen, then these can increase your risk of bruising and it may be advisable to stop taking them a few days before your treatment. It is also advisable that you do not drink alcohol the night before your treatment, for the same reason. Please do not stop taking anticoagulants if you are using them to reduce risk of cardiovascular disease, deep vein thrombosis or stroke. You can discuss this with your GP. The use of medicine such as warfarin, clopidogrel, heparins will be discussed with you at your consultation if you are taking these medications.

Please be aware of the necessary after care advice and that your schedule allows for you to follow it. It is recommended, if you have a special event or vacation coming up that you schedule your treatment at least 4 weeks in advance to allow for adjustments if necessary.

Preparation for treatment

Please attend your appointment wearing no make up as this reduces the risk of infection. Make up will need to be removed prior to the injections and you will be advised not to reapply it for 12 hours in order to reduce the risk of infection or irritation at the injection sites.

It is not advisable to have treatment if you are feeling at all unwell.

The Procedure

Small amounts of botulinum toxin are injected using a very fine needles into specific muscles of the face and/or neck. Most people do not require topical anaesthesia for this treatment.

Does it Hurt?

A very fine needle is used and generally this treatment is not described by most as painful and can be well tolerated with no anaesthetic

After the Procedure



There is usually mild to moderate irritation for an hour after treatment. Common side effects which typically resolve spontaneously within hours or days, but may persist for longer include pain or stinging when the injection is performed, localised swelling, redness or tenderness, bleeding at the sites of injection, bruising, numbness or itching of the area following injection, headache. Bruising can be a normal part of the procedure and does not represent a failure of treatment or care.

Cosmetics, strenuous exercise, gardening and alcohol consumption should be avoided for 24 hours after the procedure. Please avoid sun exposure, UV light, freezing temperatures, facial massage and saunas for 2 weeks after treatment.

A follow up email will be sent 2 weeks after the procedure was carried out. Please advise at that stage if you wish Dr Vaughan to contact you for a review. Any adjustment of your results cannot be carried out more than 4 weeks after the original appointment.

During your follow up appointment an assessment will be performed to see if you would benefit from further addition of Botulinum toxin. *Additional Botulinum toxin “top ups” cannot be performed if the remaining line or wrinkle is caused by recruitment of accessory muscles outside of those treated at the initial appointment,* such as when smiling there are some residual crows feet present due to the “ruching up” of the skin near the eye during the smile or when frowning the lateral muscles of the brow push the brow together as the muscles causing these particular actions cannot be treated whilst ensuring a good cosmetic result.

Too frequent treatments or excessive dosing of botulinum toxin may increase the risk of antibodies in the blood which may lead to failure of treatment with botulinum toxin when used for this and other conditions. A very small number of people do not respond to botulinum toxin injections as they are “immune” to the toxin. In the majority of cases once antibodies to the toxin have been produced then any further treatment will not be effective.

Additional Treatment Necessary



In some cases it may be necessary to add dermal filler to the forehead or temple to get the best results. This additional treatment will be discussed with you at your consultation but is usually due to excessively deep lines or asymmetries in the skull.

Response is usually seen within 5-10 days after injection, although sometimes 2 weeks is required to see the maximum effect. Typically the muscle action and wrinkles will return in 2-6 months. At this point a repeat treatment can be used to soften the lines again.

Contraindications

The treatment should not be performed on persons with: neurological disease such as myasthenia gravis, Eaton-Lambert syndrome, Lou Gehrig's disease, dysphagia, or who are pregnant or breastfeeding. Concurrent use of aminoglycoside antibiotics (such as streptomycin, neomycin, gentamycin, amikacin, arbekacin, kanamycin, netilmicin, panomycin, rhodostreptomycin, tobramycin, apramycin) or spectinomycin are also contraindicated. Individuals with a known hypersensitivity to any component of the formulation such as allergy to albumin or milk protein, those with bleeding disorders of any type should also not undergo treatment.

Other factors may make a person unsuitable for treatment and this list is not exhaustive. It is the responsibility of the patient to fully disclose a complete medical and drug history; suitability for treatment remains at Dr Vaughans discretion. If there are any changes in your medical history, please inform us.

Benefits

The aim is to significantly reduce the movement of the muscles causing expression lines, thus improving the appearance of such lines. Treatment may not cause the expression lines themselves to disappear completely. The expression may not be completely frozen, particularly if extreme effort is exerted to make any expression.

Limitations and Alternatives

Botulinum toxin is best at treating dynamic facial lines, such as those caused by facial muscle activity. Lines present at rest may or may not improve. A treatment may be effective for variable lengths of time with subsequent treatments, may not work as well as expected, or may not work at all. There is no guarantee given as to



the results that may be obtained.

There are alternatives which exist for the treatment of wrinkles such as topical creams, chemical peels, laser treatments, surgical removal of the frown muscles/forehead/brow lift/facelift/other surgical options, dermal fillers, skin needling treatments and radiofrequency treatments. There is also the option of no treatment at all.

Side Effects

Please notes that perfect symmetry is not achievable.

Eyelid ptosis can occur as a result of treatment. This is an unusual side effect which appears as drooping or heaviness of the eyelid which can be one eyelid or both. This can sometimes be temporarily corrected with the use of iopidine eye drops but can last the duration of the botulinum toxin treatment. In most cases the eyelid drooping resolves after 2-3 weeks.

Brow ptosis can also occur which is heaviness or lowering of the brow. Should brow ptosis occur it may take 3 or more weeks to resolve, although sometimes it can be partially corrected with the addition of more botulinum toxin in the opposing muscles. Please note that when treating the forehead we cannot unfortunately treat the lines 1-2cm above the sides of the eyebrows as this carries a higher risk of unwanted drooping of the brow. These may however be corrected using a small amount of hyaluronic acid dermal filler if desired.

It may be appropriate to add botulinum toxin to the upper forehead in cases where an excessively elevated lateral brow occurs.

Adverse reactions possibly related to the spread of botulinum toxin distant from the site of administration have been reported very rarely e.g. muscle weakness, constipation, difficulty in swallowing, food or liquid accidentally going into the lungs which in some cases may lead to pneumonia.

Any adverse reactions usually occur within a few days of treatment. They are expected to be temporary in nature and usually resolve spontaneously within a few weeks. Rarely symptoms may persist for several months.

Uncommon side effects include nausea, anxiety, dry mouth, altered skin sensation, muscle twitching or spasm in the treated area, swelling/puffiness



around the eyes, fever, lack of strength, eye pain, dry eyes, tearing, sensitivity to light, flu like symptoms, itching or dry skin, infection, muscles targeted may not be affected, rash, facial pain, drooling, difficulty in whistling, kissing and other facial movements.

The following side effects have been reported of botulinum toxin since it has been marketed; allergic reactions which can be serious (swelling of the face and airways, difficulty in breathing), loss of nerve supply or shrinkage of injected muscle, respiratory depression and/or respiratory failure, aspiration pneumonia (lung inflammation caused by accidentally breathing in food, drink, saliva or vomit), chronic disease affecting the muscles (myasthenia gravis), blurred vision, difficulties in seeing clearly, slurred speech, strabismus (squint), numbness, tingling and pain in hands and feet, fainting, pain/numbness or weakness starting from the spine, drooping of muscles on one side of the face, weakness of the facial muscles, difficulty in moving the arm or shoulder, decreased skin sensation, muscle pain, abdominal pain, diarrhoea, vomiting, loss of appetite, dry mouth, feeling sick, fever, different types of red blotchy skin rashes, feeling generally unwell, speech problems, itching, excessive sweating, hair loss, loss of eyebrows, decreased hearing, noises in the ear, feeling of dizziness or vertigo. Speak to your doctor immediately if such signs develop after treatment.

The treatment of the brow and any other area other than the frown lines or crows feet are not licenced indications. Your doctor is able to perform these treatments "off-label" but the product manufacturer has no liability should a complication arise when this medicine is used for indications that have not been licenced.

Known significant risks have been disclosed, yet the theoretical risk of unknown complications does exist.

Future Treatments

It is recommended you have the treatment performed every 3-6 months for 2 years and thereafter every 6 months. It is preferable to allow the muscle to work again completely before performing the treatment again as this will help to decrease the risk of muscle atrophy leading to the appearance of a flatter forehead. Too frequent treatments or excessive dosing of botulinum toxin may increase the risk of



antibodies in the blood which may lead to failure of treatment with botulinum toxin when used for this and other conditions.

Costs

A consultation fee applies in order to assess suitability for the treatment and covers a comprehensive assessment and an informed consent discussion. The fee for botulinum toxin treatment is variable and depends on treatment type and prescription. It is not covered by health insurance. Adjustments of the original procedure will be performed within 4 weeks of the original treatment at no cost but unfortunately cannot be provided outside this time window.

Payment rendered is considered to be in return for application of botulinum toxin and whilst every effort is made to satisfy aesthetic concerns there is no guarantee of outcome, therefore refunds cannot be made under any circumstances.

Dr Vaughan reserves the absolute right to refuse or cancel treatment based upon an assessment of findings on the treatment day.

