



INFORMED CONSENT FOR BOTULINUM TOXIN TREATMENT

NAME: _____

DATE OF BIRTH: _____

PHONE _____

The purpose of this form is to provide written information regarding the risks, benefits and alternatives of the administration of BOTULINUM TOXIN A (Botox, Xeomin, Dysport).

Botulinum toxin A is used in the correction of mild to moderate facial lines, wrinkles, muscle tension and headaches related to muscular movement.

This material serves as a supplement to the discussion you have with your dentist. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your dentist prior to signing the consent form.

Botulinum Toxin A has been approved by the TGA to be administered by a properly trained clinician, for the treatment of glabellar lines and primary hyperhidrosis of the axillae on 9 October 2003. While the TGA has not approved injections to treat dental related conditions in other areas of the face, qualified physicians or dentists may perform these “**off-label**” procedures.

Botulinum Toxin A is a neurotoxin produced by the bacterium Clostridium A. It can relax the muscles of the face and neck which cause wrinkles associated with facial expressions or facial pain relating to Temporomandibular dysfunction.

PROCEDURE

Therapeutic application includes injection into areas:

- A) Masseter muscle (primary muscle relating to clenching)
- B) Temporalis muscle (associated with clenching as well as temporal headaches)
- C) Radial Lip Lines (smokers lines)
- D) Marionette lines (which can become more pronounced following loss of back teeth, or ill-fitting dentures and fungal infection at the corners of the mouth (angular cheilitis)).

The procedure takes about 15-20 minutes and the results can last up to 3-4 months. With repeated treatments, the results may tend to last longer however this differs patient to patient dependent upon dose, metabolism amongst other factors. Serial treatments will be required to maintain results or to reduce masseter hypertrophy.

TREATMENT ALTERNATIVES

Alternative treatments include physiotherapy and/or fabrication of an occlusal splint to help relax the muscles of mastication, which may reduce facial pain, and act as a barrier to further wear or cracking of the teeth.

RIGHT TO DISCONTINUE TREATMENT

I understand that I have the right to discontinue treatment at any time.



RISKS AND COMPLICATIONS

No procedure is completely risk-free.

1. Post treatment discomfort, swelling, redness, and bruising. Most people have lightly swollen pinkish bumps at the injection site for a few hours or even several days.
2. Minor ptosis (drooping) of the eyebrow or eyelid or drooping of the mouth occurs in approximately 2% of injections, this usually lasts 2-3 weeks however may persist for 3-4 months until the toxin is completely metabolised. While local weakness of the injected muscles is representative of the expected pharmacological action of neurotoxin, weakness of adjacent muscles may occur as a result of the spread of the toxin. This could result in temporary blurring of vision
3. Under-correction (not enough effect) or overcorrection (too much effect)
4. Headache
5. Skin tightness
6. Numbness or feeling of pins and needles
7. Nausea
8. Facial Asymmetry
9. Post treatment bacterial, and/or fungal infection requiring further treatment.
10. Allergic reaction

RESULTS

When small amounts of purified botulinum toxin are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 3 – 10 days and usually lasts up to 3 months but can be shorter or longer.

The goal of toxin injection is to paralyse muscles, so that the tension in them is reduced. This in turn can reduce load and discomfort in the heavy grinding muscles of the jaws, and reduce wrinkles in the small muscles around the oral tissues. In a very small number of individuals, the results are unsatisfactory or not as significant as usual, and there are some individuals who do not respond at all. Treated muscles will not be able to be used the same manner as prior to injection, but this will reverse after a period of months (at which time re-treatment is appropriate).

ACKNOWLEDGEMENT AND CONSENT

Please initial prior to signing consent

	The details of this procedure have been explained to me in terms I understand.
	I understand that Botulinum Toxin will be injected into specific sites as discussed with my dentist for a therapeutic effect. I understand that some of this treatment is considered “off label” and I voluntarily consent to treatment for facial dynamic wrinkles, TMJ dysfunction, bruxism and types of orofacial pain including headaches and migraines.
	Alternative methods and their benefits and disadvantages have been explained to me.
	I understand that this is an "elective" procedure and that payment is my responsibility and is expected at the time of treatment.

	I have provided my dentist with a complete medical history, including all of the medications, natural treatments and tablets that I might be taking.
	I have informed the dentist of all my known allergies.
	I do NOT have any of the following conditions 1. Defective neuromuscular transmission disorders including but not limited to Myasthenis Gravis, Multiple Sclerosis, Lambert-Eaton Syndrome, Amyotrophic Lateral Sclerosis (ALS), or Parkinson's. 2. Infection at the site of injection 3. Glaucoma 4. Pregnancy 5. Lactation (breast feeding) 6. Any known allergies to the toxin ingredients, or to human albumin
	I understand that possible side effects include headaches, pain, burning or redness at the site of injection, some local muscle tenderness and in rare cases droopiness of an eyelid, lack of feeling and nausea.
	I understand that I must stay in the erect posture and that I must not manipulate the area(s) of the injections for the 2 hours post-injection period.
	I have been advised to seek immediate medical attention in the event of vision, swallowing, speech, or respiratory disorders.
	I have had an opportunity to ask any questions I may have in connection with the treatment and to discuss my concerns with my doctor and my questions have been answered to my satisfaction.
	I accept the risks and complications of the procedure and I understand that no guarantees are implied as to the outcome of the procedure.
	I understand that it is important for me to abide by the specific prescriptions and instructions given by my dentist.
	I understand that regardless of what had been explained to me or my expectations, results and experiences vary from patient to patient.
	I also state that I read and write in English.
	I certify that I have read and understand this agreement and that all spaces for initials were filled prior to my signature.

PRINT NAME: _____ DATE: _____

PATIENT SIGNATURE: _____ DATE: _____



I certify that I have explained the nature, purpose, benefits, risks, complications and alternatives of the proposed procedure to the patient. I have answered fully, and I believe that the patient fully understands what I have explained.

DOCTOR SIGNATURE: _____ DATE: _____