

SPAMEDiCA

BOTOX INJECTIONS

INFORMED CONSENT BOOKLET

INSTRUCTIONS

This is an informed-consent document that has been prepared by Dr. Mulholland to help inform you about Botox injections, the risks, and alternative treatment. During your consultation, you will review the potential benefits of Botox injections, the alternatives and all the points in this booklet. You will be able to ask any questions and be provided with answers to these questions to the best of our ability. It is important that you read this information again carefully and completely. Only when you have no questions or concerns do you initial each page, indicating that you have read and fully understood all the items it discusses. When you arrive at the end of this booklet, sign the consent for the procedure as proposed by Dr. Mulholland or your nurse injector. If you have any remaining questions, do not initial or sign the consent until they have been answered to your satisfaction.

INTRODUCTION

BOTOX injections are a non-surgical procedure designed to paralyze the portions of overactive facial muscles that cause deep furrows, creases and fine wrinkles in the face. BOTOX is a sterile, vacuum-dried form of purified botulinum neurotoxin type A complex, produced from a culture of the A strain of bacteria called Clostridium Botulinum. Although the Clostridium bacteria causes botulism, the BOTOX extract does not. The BOTOX extract is the purified, sterilized product from the bacteria and is a potent localized muscle, paralytic agent. BOTOX contains a small amount of pasteurized human albumin. No cases of viral diseases have even been identified for albumin. BOTOX has been used safely for many years in the treatment of muscle disorders of the eyes and voicebox. Its most recent application has been in the treatment of cosmetic wrinkles, creases and lines in the face. BOTOX is a simple injection performed in the office by Dr. Mulholland, one of the clinic dermatologists or a SpaMedica nurse injector. The improvement in the wrinkles begins approximately 5-7 days after the injection and lasts for 3-6 months. It may be repeated indefinitely.

ALTERNATIVE TREATMENT

Alternative forms of treatment or management, consist of not treating the wrinkles or creases and continuing to use camouflage makeup. Topical wrinkle creams or Retin A may add some minor improvement. Microdermabrasion and Pulsed Light therapy, called WrinkleLIGHT and/or Photofacial can provide noticeable improvement in fine wrinkles without any recovery or down time (ask our staff about these treatments) and are often performed in conjunction with BOTOX. Injectable treatments such as Collagen, Artecoll, Hyaluronic Acids, and/or Microfat may help fill out the wrinkle. Implantable substances such as Softform (Gortex) or Alloderm may help fill out a defect. Topical laser treatment (CO₂ or Erbium) may improve or eliminate certain wrinkles. Cosmetic plastic surgery procedures such as Endoscopic Browlift, Eyelid Tucks or Face-Neck Lifts may also improve the creases or wrinkles.

POTENTIAL BENEFITS OF BOTOX

Prolonged softening of the fine lines, wrinkles, creases and furrows of the forehead, eyes and neck, creating a more serene-looking face with less active muscles and creases.

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RISKS OF BOTOX INJECTIONS

Pain/Discomfort- There is a minor degree of discomfort from the small-gauge needle that is inserted under the skin. There is a slight burning discomfort as the BOTOX is injected into the muscle. Most patients find the process less painful than an immunization. The BOTOX treatment only takes a few minutes to complete and is performed in the office.

Bruising/Swelling- Most patients have some swelling in the injection area for a couple of hours. It is rare to develop bruising after, but if this were to occur, it should disappear in 7-10 days and can be camouflaged with makeup immediately following treatment.

Infection- Like any injection technique, an infection may rarely occur (less than 0.5% risk) and can usually be treated with an oral antibiotic. Severe infections, although exceedingly rare, may require a drainage procedure or surgery.

Additional Treatment – If you feel that additional relaxation is desired, this will be addressed at your 2 week follow up appointment. There will be an additional charge for product used.

Long-term Effects- The duration of improvement with the BOTOX varies between patients, but generally, 3-6 months of decreased muscle activity and wrinkle improvement may be achieved. Repeat treatments can be performed but, prolonged use over many years may result in a permanent weakness of muscle function.

Pregnancy- BOTOX should not be used while pregnant as there is a risk of premature delivery. If there is any chance that you may be pregnant, you should first exclude the possibility with a pregnancy blood test, or not have the BOTOX.

Lactation- There is no known risk of BOTOX during lactation but, if you are concerned, we recommend postponing your BOTOX until you have completed breastfeeding.

Asymmetry- When two sides of the face are being treated for the same problem, there may be some asymmetries that result between the BOTOX performed on one side and the same treatment on the other side.

Functional Problems- Although extremely rare, if the BOTOX treatment is too effective or there is subcutaneous migration of the substance, functional or esthetically displeasing effects may occur such as Brow Ptosis (drooping of the brow), Eyelid Ptosis (subtle drooping of an eyelid), Diplopia (double vision), Lagophthalmous (weakness of eye closure) or a smile droop. Fortunately, these side-effects are extremely rare and temporary (as the BOTOX effect wears off in a few months). Depending upon the area treated, smile and lip asymmetry, failure of adequate lip closure, articulating abnormalities, swallowing and coughing may be affected.

General Body Symptoms- These occur very rarely (less than 0.1%) but can include skin rash, itchiness, general malaise, headaches, drowsiness, fever or flu-like symptoms that last for several hours or several days. These symptoms are temporary and may be remedied with over the counter products you would normally take for minor aches and discomfort.

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ADDITIONAL TREATMENT NECESSARY

Should any of the aforementioned or other complications occur, additional procedures or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited and those you have just reviewed, are those risks particularly associated with BOTOX injections. Other complications and risks can occur but are even more uncommon.

The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

HEALTH INSURANCE

Most health insurance companies including OHIP, exclude coverage for cosmetic surgical operations such as BOTOX injections. Please carefully review your health insurance subscriber-information pamphlet. Generally, complications arising from such surgery are covered by Health Insurance.

FINANCIAL RESPONSIBILITES

The cost of surgery involves several charges for the services provided. The total includes fees charged by Dr. Mulholland, the cost of surgical supplies, anaesthesia, nursing costs and outpatient facility charges. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or facility day-surgery charges involved with revisionary surgery would also be your responsibility.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition, along with disclosure of risks and alternative treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

What Dr. Mulholland has discussed with you and included again in this booklet are the material risks, both common and uncommon, that he feels a reasonable person would want to know, understand and consider in trying to decide if BOTOX injections are something they would like to proceed with. However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Dr. Mulholland may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information contained on this and all preceding pages carefully and have all of your questions answered before signing the consent on the next page. Questions and concerns can be addressed by contacting the office in Toronto at 416-922-2868 and speaking with one of the SpaMedica nurse injectors.

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CONSENT FOR PROCEDURE AND/OR TREATMENT

I have received the following information/informed consent booklet for:

1. I hereby authorize Dr. Mulholland and/or such assistants as may be selected to perform the following procedure and/or treatment:

2. I recognize that during the course of the procedure/treatment unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and/or assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is commenced.
3. I consent to the administration of such anaesthesia considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, injury and sometimes death.
4. As part of the requirements of the Canadian Association for Accreditation of Ambulatory Surgical Facilities, my chart may be subject to a peer review for quality control.
5. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
6. I consent to the photographing of appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by them.
7. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
8. I understand that the signature of the witness (if a non-physician) on this document indicates only that the signing of my name has been observed and not that the witness has necessarily provided information regarding the procedure.
9. **IT HAS BEEN EXPLAINED TO ME BY MY PHYSICIAN AND/OR ASSISTANTS IN A WAY THAT I UNDERSTAND:**
THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
THERE ARE RISKS TO THE PROCEDURE/TREATMENT PROPOSED
ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

**I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).
I AM SATISFIED WITH THE EXPLANATION.**

Patient or Person Authorized to Sign for Patient

Please Print Name Here

DATE

WITNESS