



Pacific Clinic

PENILE BOTOX INJECTION PROCEDURE **CONSENT FORM**

INFORMED CONSENT:

- I have received information about my condition, the proposed treatment, alternatives, and related risks. This form contains a summary of this information. I have received an explanation of any unfamiliar terms and have been offered the opportunity to ask questions.
- I have not received any promise, guarantee or warranty that my undergoing the Penile Botox Injection procedure will achieve a particular result.
- I fully understand that individual results do vary, and that the Pacific Clinic, nor its physicians, assumes no responsibility for failure to achieve a desired result.
- I understand I may refuse consent and I GIVE MY INFORMED AND VOLUNTARY CONSENT to the proposed procedure and the other matters shown below.
- I also consent to the performance of any additional procedures determined during a procedure to be in my best interests and where delay might impair my health.

THE TREATMENT:

Penile Botox Injection procedure - Botulinum Toxin A is a neurotoxin produced by the bacterium Clostridium A. After preparation, Botulinum Toxin A is injected into the corpus cavernosum of the penis to improve penis tissue health and enhance erectile function or penis size.

- A. I authorize the physicians at the Pacific Clinic to treat my condition, including performing further diagnosis and the procedures described below, and taking any needed photographs.
- B. I understand the proposed Penile PRP Injection procedure to be: a procedure wherein Botulinum Toxin A is injected into the corpus cavernosum of the penis to improve penis tissue health and enhance erectile function or penis size.
- C. I understand that the use of Botulinum Toxin A in this procedure is an “off-label” use, and no promise or representation, guarantee or warranty regarding its use, benefit or



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other quality is made. No representations that the use of this product and this procedure is approved by the FDA or any other agency of the federal or state government is made.

- D. I understand that Botulinum Toxin A is made from donated human plasma and may contain viruses or other infectious agents. I also understand that donated plasma is tested and treated to reduce the risk of contamination, but there is still a small possibility it could transmit disease.
- E. I do not have any allergies to the listed toxin ingredients, or to human albumin. Alternatives and options to the procedure have been fully explained to me.
- F. Before undergoing this procedure, understanding the risks is essential. No procedure is completely risk-free. The following risks may occur, but there may be unforeseen risks and risks that are not included on this list. Some of these risks, if they occur, may necessitate hospitalization, and/or extended outpatient therapy to permit adequate treatment. It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to:

Common:

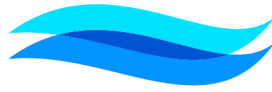
- Post-procedure pain
- Swelling
-

Rare:

- Bleeding
- Hematoma
- Nodule formation

Very Rare:

- Infections
- Urinary retention
- Allergic reactions

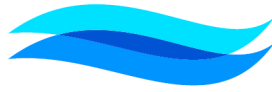


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- Mental preoccupation of the penis
- Alteration of the function of the penis
- Sexual function alteration
- Increased/worsening nocturia (waking up several times at night to urinate)
- Change in urinary stream
- Need for subsequent surgery
- Alteration of penile sensations
- Scar formation (penile)
- Local tissue infarction and necrosis
- Fatigue
- Alteration of bladder dynamics
- Prolonged or intractable pain
- Alteration of the male sexual response cycle
- Psychological alterations
- Relationship problems
- Decreased sexual function
- Possible hospitalization for treatment of complications
- Lidocaine toxicity
- Anesthesia reaction
- Embolism
- Depression
- Reactions to medications including anaphylaxis
- Nerve damage
- Permanent numbness

POST TREATMENT SIDE EFFECTS:

- discomfort, swelling, redness, and bruising
- Post treatment bacterial, and/or fungal infection requiring further treatment
- Allergic reaction: hives, itching; wheezing, difficult breathing; feeling like you might pass out; swelling of your face, lips, tongue, or throat
- Transient headache
- Flu-like symptoms, fever, chills, body aches
- unusual or severe muscle weakness (especially in a body area that was not injected with the medication)
- loss of bladder control



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- hoarse voice, trouble talking or swallowing
- drooping eyelids or eyebrows
- vision changes, eye pain, severely dry or irritated eyes (your eyes may also be more sensitive to light)
- chest pain or pressure, pain spreading to your jaw or shoulder, irregular heartbeats
- pain or burning when you urinate, trouble emptying your bladder
- sore throat, cough, chest tightness, shortness of breath
- eyelid swelling, crusting or drainage from your eyes, problems with vision;
- painful or difficult urination
- neck pain, back pain, pain in your arms or legs
- cold symptoms such as stuffy nose, sneezing, sore throat
- increased sweating in areas other than the underarms
- bruising, bleeding, pain, redness, or swelling where the injection was given.

SIMILARITY OF VIAGRA:

- Because Botox in the Penis works similarly to Viagra (relaxation of the smooth muscle controlling blood flow to the penis), the following side effects of Viagra could also be seen when injecting Botox into the penis.
- The **most common adverse reactions** reported **in clinical trials (≥ 2%)** are headache, flushing, dyspepsia, abnormal vision, nasal congestion, back pain, myalgia, nausea, dizziness, and rash.
- The following events occurred **in <2% of patients** in controlled clinical trials; a **causal relationship to VIAGRA is uncertain**. Reported events include those with a plausible relation to drug use.
- **Body as a Whole**: face edema, photosensitivity reaction, shock, asthenia, pain, chills, accidental fall, abdominal pain, allergic reaction, chest pain, accidental injury.
- **Cardiovascular**: angina pectoris, AV block, migraine, syncope, tachycardia, palpitation, hypotension, postural hypotension, myocardial ischemia, cerebral thrombosis, cardiac arrest, heart failure, abnormal electrocardiogram, cardiomyopathy.



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- Digestive: vomiting, glossitis, colitis, dysphagia, gastritis, gastroenteritis, esophagitis, stomatitis, dry mouth, liver function tests abnormal, rectal hemorrhage, gingivitis.
- Hemic and Lymphatic: anemia and leukopenia.
- Metabolic and Nutritional: thirst, edema, gout, unstable diabetes, hyperglycemia, peripheral edema, hyperuricemia, hypoglycemic reaction, hypernatremia.
- Musculoskeletal: arthritis, arthrosis, myalgia, tendon rupture, tenosynovitis, bone pain, myasthenia, synovitis.
- Nervous: ataxia, hypertonia, neuralgia, neuropathy, paresthesia, tremor, vertigo, depression, insomnia, somnolence, abnormal dreams, reflexes decreased, hypesthesia.
- Respiratory: asthma, dyspnea, laryngitis, pharyngitis, sinusitis, bronchitis, sputum increased, cough increased.
- Skin and Appendages: urticaria, herpes simplex, pruritus, sweating, skin ulcer, contact dermatitis, exfoliative dermatitis.
- Special Senses: sudden decrease or loss of hearing, mydriasis, conjunctivitis, photophobia, tinnitus, eye pain, ear pain, eye hemorrhage, cataract, dry eyes.
- Urogenital: cystitis, nocturia, urinary frequency, breast enlargement, urinary incontinence, abnormal ejaculation, genital edema and anorgasmia.
- I also understand that there may be other RISKS OR COMPLICATIONS, OR SERIOUS INJURY from both known and unknown causes. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the risks of the procedure.

ALLERGIES & NEUROLOGIC DISEASE:

- I do not have any significant neurologic disease including but not limited to the following: myasthenis gravis, multiple sclerosis, Lambert-Eaton syndrome, Amyotrophic Lateral Sclerosis (ALS, or "Lou Gehrig's disease") or Parkinson's disease.
- I have not had any of the following: Botulinum Toxin A injections in the last 4 months, side effect after prior use of Botulinum Toxin A, breathing disorder such as asthma or emphysema, problems with swallowing, facial muscle weakness (droopy eyelids, weak forehead, trouble raising my eyebrows), change in the normal appearance of my face, bleeding problems or surgery.



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CONSENT FOR ANESTHESIA:

- I consent to the administration of such local anesthetics as may be considered necessary by the physician in charge of my care.
- I understand that the risks of local anesthesia include: local discomfort, swelling, bruising, allergic reactions to medications, and seizures from lidocaine.

RIGHT TO DISCONTINUE TREATMENT:

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

PAYMENT:

- I understand that this is an "elective" procedure, and that payment is my responsibility and is expected at the time of treatment.

PATIENT CERTIFICATION / ELECTIVE PROCEDURE:

- By signing below, I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents of this form. I understand the information on this form and give my consent to what is described above and to what has been explained to me.
- My questions have been answered satisfactorily. 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 also certify that if I have any changes in my medical history, I will notify the doctor/healthcare professional who treated me immediately. I also state that I read and write in English.

PATIENT NAME (Print) :



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PATIENT SIGNATURE :

TODAY'S DATE:
