informed consent

Instructions

This is an informed-consent document which has been prepared to help inform you concerning cosmetic Botulina-Origin Neurotoxin Type A neurotoxin injections, their risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure as proposed by your physician

Instruction

Clostridia botulina bacteria produce a class of chemical compounds known as “toxins.” The Botulina-Origin Neurotoxin Type A “BONTA” is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle.

BONTA has been used to treat functional disorders that involve muscle spasticity and cosmetic conditions of muscle-induced skin wrinkles of the forehead. It has been used in an “off-label” manner to treat facial wrinkles, excessive sweating, migraine headaches, and colorectal disorders.

Cosmetic BONTA intramuscular injections are customized for every patient, depending on their needs. BONTA cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups or treat other conditions.

US Food and Drug Black Box Warning regarding the administration of neurotoxins:

Distant Spread of Toxin Effect Post marketing reports indicate that the effects of all Botulina toxin products may spread from the area of injection to produce symptoms consistent with Botulina toxin effects. This may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injections. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in unapproved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

Alternative Treatments

Alternative forms of management include not treating the skin wrinkles by any means. Improvement of skin wrinkles may be accomplished by other treatments or alternative types of surgery. Minor skin wrinkling may be improved through chemical skin-peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of treatment.

Risks Of Bonta (Botulina Type A Toxin) Injections

Every procedure involves a certain amount of risk, and it is important that you understand the risks. Your decision to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following complications, you should discuss each of them with your physician to make sure you understand the risks, potential complications, and consequences of BONTA injections to improve facial wrinkling.

Bleeding - It is possible, though unusual, to have a bleeding episode from a BONTA injection. Bruising may occur. Serious bleeding around the eyeball during deeper BONTA injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Do not take any aspirin or anti-inflammatory medications for seven days before BONTA injections, as this may contribute to a greater risk of bleeding.

Damage to deep structures - Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the course of BONTA injection. Injury to deeper structures may be temporary or permanent.

Pain - Discomfort associated with BONTA injections is usually short in duration. It is possible to have a fainting episode (vasovagal) from discomfort or anxiety about the injections. Headaches have been reported post BONTA injection.

Migration of BONTA - BONTA may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects (see FDA “Black Box” warning page 1).

Skin disorders - Skin rash and swelling may rarely occur following BONTA injection.

Eye-related problems:

- Corneal exposure problems - Some patients experience difficulties closing their eyelids after BONTA injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.
- Dry eye problems - Individuals who normally have dry eyes may be advised to use special caution in considering BONTA injections around the eyelid region.
- Drooping Eyelid (Ptosis) - Muscles that raise the eyelid may be affected by BONTA, should this material migrate downward from other injection areas.
- Double Vision - Double vision may be produced if the BONTA migrates into the region of muscles that control movements of the eyeball.
- Eyelid Ectropion - Abnormal looseness of the lower eyelid can occur following BONTA injection.
- Other Eye Disorders - Functional and irritative disorders of eye structures may rarely occur following BONTA injections.
- Blindness - Blindness is extremely rare after BONTA injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury.

Asymmetry -The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to BONTA injection.

Unknown risks - The long term effect of BONTA on tissue is unknown. There is the possibility that additional risk factors may be discovered.

Unsatisfactory result - There is the possibility of a poor or inadequate response from BONTA injection. Additional BONTA injections may be necessary.

Allergic reactions - As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

Antibodies to BONTA - Presence of antibodies to BONTA may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BONTA is unknown.

Long-term effects - Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to BONTA injections. BONTA injection does not arrest the aging process or produce permanent tightening of the eyelid region. Future surgery or other treatments may be necessary.

Risks of BONTA Injections, continued

Infection - Infection is extremely rare after BONTA injection. BONTA is contraindicated if there is an infection at the injection site.

Pregnancy and nursing mothers - Animal reproduction studies have not been performed to determine if BONTA could produce fetal harm. It is not known if BONTA can be excreted in human milk.

Drug Interactions - The effect of BONTA may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Off-label usage of BONTA - BONTA, depending on its manufacturer is labeled for specific use. The use of BONTA for other conditions and disorders would be considered “off-label” usage by your physician. FDA defines off label use as, “Use for indication, dosage form, dose regimen, population or other use parameter not mentioned in the approved labeling.” The FDA recognizes that off label use of drugs by prescribers is often appropriate and may receive endorsement from published literature. BONTA may be used according to a physician’s practice beyond the manufacturer’s time limit following reconstitution. Contents of a BONTA vial may be split into sub-units and given to multiple patients, using appropriate sterile technique and precautions.

Health Insurance

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Please carefully review your health insurance subscriber information pamphlet.

Additional Treatment Necessary

There are many variable conditions in addition to risk and potential complications that may influence the long term result of BONTA injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BONTA injections. Other complications and risks can occur but are even more uncommon. Should complications occur, other treatments may be necessary. 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.

Financial Responsibilities

The cost of BONTA injection may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the

cost of the BONTA product. It is unlikely that BONTA injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from BONTA injections. You may require additional treatments with BONTA to enhance the effect of the initial treatment.

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 forms of 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.

However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information which is based on all of the facts pertaining to 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 carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Cabbabe and such assistants as have been selected to perform the following procedure or treatment:

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I have received the following information sheet:

INFORMED-CONSENT for BONTA Injection
Medication Guide Document for Neurotoxins

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and 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 begun.
3. I consent to the administration of local anesthesia (regional nerve blocks, direct infiltration or topical) to diminish discomfort of injection.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
7. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
   a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
   b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
   c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

   I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-7). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

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Date Witness

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