

INFORMED-CONSENT-BOTOX/DYSPOORT/XEMOIN/JEUVEAU INJECTION (*Botulinum* Toxin Type A)

INSTRUCTIONS

This is an informed-consent document which has been prepared to help your physician inform you concerning BOTOX/DYSPOORT/XEMOIN/JEUVEAU ® (*Botulinum* Toxin Type A, Allergan/Medicis) injection, its 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.

INTRODUCTION

Clostridia botulinum bacteria produce a class of chemical compounds known as "toxins". The *Botulinum* Type A Toxin (BOTOX/DYSPOORT/XEMOIN/JEUVEAU, Allergan/Medicis) 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. The duration of muscle paralysis generally lasts for approximately three to four months. Continuing treatments are necessary in order to maintain the effect of BOTOX/DYSPOORT/XEMOIN/JEUVEAU over time.

BOTOX/DYSPOORT/XEMOIN/JEUVEAU has been approved to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder with the neck) and motor disorders of the facial nerve (VII cranial nerve). As of April 2002, it has been FDA approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups. Other areas of the face and body such as crows feet wrinkles and neck bands may be treated in an "off-label" fashion. BOTOX/DYSPOORT/XEMOIN/JEUVEAU has also been used "off-label" to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region, forehead, and neck.

BOTOX/DYSPOORT/XEMOIN/JEUVEAU cannot stop the process of aging. It can, however, temporarily diminish the look of wrinkles caused by muscle groups. BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

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 such as a blepharoplasty, face or brow lift when indicated. Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion). 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 medical or surgical treatment.

RISKS of BOTOX/DYSPOORT/XEMOIN/JEUVEAU (Botulinum Type A Toxin) Injections

Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice 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 BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections.

Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia (lack of energy), generalized muscle weakness, diplopia (double vision), blurred vision, ptosis (eyelid droop), dysphagia (trouble swallowing), dysphonia (trouble speaking), dysarthria (trouble saying words clearly), urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. 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

Risks of BOTOX/DYSPOORT/XEMOIN/JEUVEAU Injections, continued

to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dystonia and at lower doses.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when Botox or Dysport has been used at recommended doses to treat underarm sweating, blepharospasm, strabismus, or when used for cosmetic purposes.

Bleeding- It is possible, though unusual, to have a bleeding episode from a BOTOX/DYSPOORT/XEMOIN/JEUVEAU injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper BOTOX/DYSPOORT/XEMOIN/JEUVEAU 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 BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections, as this may contribute to a greater risk of a bleeding problem.

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

Corneal exposure problems- Some patients experience difficulties closing their eyelids after BOTOX/DYSPOORT/XEMOIN/JEUVEAU 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 BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections around the eyelid region.

Migration of BOTOX/DYSPOORT/XEMOIN/JEUVEAU- BOTOX/DYSPOORT/XEMOIN/JEUVEAU may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects. BOTOX/DYSPOORT/XEMOIN/JEUVEAU has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia)

Drooping Eyelid (Ptosis)- Muscles that raise the eyelid may be affected by BOTOX/DYSPOORT/XEMOIN/JEUVEAU, should this material migrate downward from other injection areas. It more commonly occurs when BOTOX/DYSPOORT/XEMOIN/JEUVEAU is used to treat spastic eyelid muscles or blepharospasm.

Double-Vision- Double-vision may be produced if the BOTOX/DYSPOORT/XEMOIN/JEUVEAU material migrates into the region of muscles that control movements of the eyeball.

Eyelid Ectropion- Abnormal looseness of the lower eyelid can occur following BOTOX/DYSPOORT/XEMOIN/JEUVEAU injection(s).

Other Eye Disorders- Functional and irritative disorders of eye structures may rarely occur following BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections.

Blindness- Blindness is extremely rare after BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. According to Allergan/Medicis, the company that produces BOTOX/DYSPOORT/XEMOIN/JEUVEAU, over a period of 10 years of BOTOX/DYSPOORT/XEMOIN/JEUVEAU administration, complications of blurred vision, retinal vein occlusion, and glaucoma have been reported in three patients. The occurrence of eye problems appears to be very rare.

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 BOTOX/DYSPOORT/XEMOIN/JEUVEAU injection.

Pain- Discomfort associated with BOTOX/DYSPOORT/XEMOIN/JEUVEAU injections is usually of a short duration.

Risks of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU Injections, continued

Unsatisfactory result- There is the possibility of a poor or inadequate response from BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injection(s). Additional BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

Allergic reactions- As with all biologic products, allergic and systemic life-threatening anaphylactic reactions may occur. Allergic reactions may require additional treatment. Systemic anaphylactic reactions require immediate medical care.

Note: DYSPOSPORT IS CONTRAINDICATED IN THOSE WHO ARE ALLERGIC TO COW'S MILK PROTEIN

Antibodies to BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU- Presence of antibodies to BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU is unknown.

Infection- Infection is extremely rare after BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injection. Should an infection occur, additional treatment including antibiotics may be necessary.

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 BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injections. Future surgery or other treatments may be necessary. BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injection does not arrest the aging process or produce permanent tightening of the eyelid region. Continuing treatments are necessary in order to maintain the effect of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU over time.

Pregnancy and nursing mothers- Animal reproduction studies have not been performed to determine if BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU could produce fetal harm. It is not known if BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU treatments.

Drug Interactions- The effect of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

Skin disorders- Local or systemic skin rash, itching, and swelling may rarely occur following BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injection.

Neuromuscular disorders- Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia gravis, motor neuropathies) may be at greater risk of clinically significant side effects from BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU.

Migraine headache and other medical disorders- BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of off-label BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU treatment for migraine headaches and other medical disorders may be variable and improvement may not occur following BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU treatments.

Unknown risks- The long term effect of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU on tissue is unknown. The risk and consequences of accidental intravascular injection of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU is unknown and not predictable. There is the possibility additional risk factors may be discovered.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical procedures and treatments or any complications that might occur from the same. Health insurance companies may not pay for BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injections used to treat medical conditions. 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 BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or 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.

Risks of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU Injections, continued

FINANCIAL RESPONSIBILITIES

The cost of BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU 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 BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU material itself. It is unlikely that BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU 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 BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU injections.

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 this page.

CONSENT FOR SURGERY/ PROCEDURE or TREATMENT

1. I hereby authorize Dr. Adam Scheiner to perform the following procedure or treatment:

 BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU
INJECTIONS: _____

I have received the following information sheet:

INFORMED-CONSENT for BOTOX/DYSPOSPORT/XEMOIN/JEUVEAU Injection

2. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
3. 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.
4. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
5. **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 AS DESCRIBED ABOVE. I AM SATISFIED WITH THE EXPLANATION.

Signature of Patient or Person Authorized to Sign for Patient

Printed Name

Date