INFORMED CONSENT FOR DYSPORT TREATMENT

What is the most important information I should know about DYSPORT®?
DYSPORT® may cause serious side effects that can be life threatening. Call you doctor or get medical help right away if you have any of these problems after treatment with DYSPORT®:
> Problems swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of DYSPORT® usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with DYSPORT®.
> People with certain breathing problems may need to use muscles in their neck to help them breathe. These patients may be at greater risk for serious breathing problems with DYSPORT®.
> Swallowing problems may last for several weeks. People who can not swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving DYSPORT® have the highest risk of getting these problems.
> Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:

> loss of strength and muscle weakness all over the body
> double vision > hoarseness or change or loss of voice (dysphonia)
> trouble saying words clearly (dysarthria)
> loss of bladder control
> trouble breathing
> trouble swallowing

These symptoms can happen hours to weeks after you receive an injection of DYSPORT®. These problems could make it unsafe for you to drive a car or do other dangerous activities.

What is DYSPORT®?
DYSPORT® is a prescription medicine that is injected into muscles and used:
> to improve to the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary). Frown lines (wrinkles) happen because the muscles that control the facial expression are used often (muscle tightening over and over). After DYSPORT® is injected into the muscle that control facial expression, the medicine stops the tightening of these muscles for up to 4 months. It is not known whether DYSPORT® is safe or effective in children under 18 years of age. It is not know whether DYSPORT® is safe or effective for the treatment of other types of muscle spasms. It is not known whether DYSPORT™ is safe or effective for the treatment of other wrinkles.

Who should not take DYSPORT®?
Do not take DYSPORT® if you:
> are allergic to DYSPORT® or any of the ingredients in DYSPORT®
> are allergic to cow’s milk protein

> had an allergic reaction to any other botulinum toxin product such as Myobloc®* or Botox®*
> have a skin infection at the planned injection site

What should I tell my doctor before taking DYSPORT®?
Tell your doctor about all your medical conditions, including if you have:
> a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis [or Lambert-Eaton syndrome]).
> allergies to any botulinum toxin product
> had any side effect from any botulinum toxin product in the past
> a breathing problem, such as asthma or emphysema
> swallowing problems
> bleeding problems
> diabetes
> a slow heart beat or other problem with your heart rate or rhythm
> plans to have surgery
> had surgery on your face
> weakness of your forehead muscles (such as trouble raising your eyebrows)
> drooping eyelids
> any other change in the way your face normally looks

Tell your doctor if you:
> are pregnant or plan to become pregnant. It is not known if DYSPORT® can harm your unborn baby
> are breast-feeding or planning to breast-feed. It is not known if DYSPORT® passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using DYSPORT® with certain other medicines may cause serious side effects. Do not start any new medicines while taking DYSPORT® without talking to your doctor first. Especially tell your doctor if you:
> have received any other botulinum toxin product in the last four months
> have received injections of botulinum toxin, such as Myobloc® (Botulinum Toxin Type B) or Botox® (Botulinum Toxin Type A)* in the past; be sure your doctor knows exactly which product you received
> have recently received an antibiotic by injection
> take muscle relaxants
> take an allergy or cold medicine
> take a sleep medicine
Ask you doctor if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take DYSPORT®?

> DYSPORT® is an injection that your doctor will give you
> DYSPORT® is injected into the affected muscles
> Your doctor may give you another does of DYSPORT® after 12 weeks or longer, if it is needed > If you are being treated for Cervical Dystonia, your doctor may change your dose of DYSPORT® until you and your doctor find the best dose for you
> The dose of DYSPORT® is not the same as the dose of any other botulinum toxin product

What should I avoid while taking DYSPORT®?
DYSPORT™ may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking DYSPORT®. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

What are the possible side effects of DYSPORT®?
DYSPORT® can cause serious side effects. Other side effects of DYSPORT® include:
> dry mouth
> injection site discomfort or pain
> tiredness
> headache
> neck pain
> muscle pain
> eye problems: double vision, blurred vision, decreased eyesight, problems with focusing the eyes (accommodation), drooping eyelids, swelling of the eyelids
> allergic reactions.

Symptoms of an allergic reaction to DYSPORT® may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint
Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DYSPORT®. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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
- 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.

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 DYSPORT TREATMENT

1. I _____ hereby authorize Emile Baker, APRN to perform the following procedure or treatment: Dysport injections.
2. I have received the following information sheet: Informed Consent for Dysport Treatment
3. I recognize that during the course of the treatment, unforeseen conditions may necessitate different treatments than those above. I therefore authorize the above Nurse Practitioner to perform such other treatments that are in the exercise of 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 provider at the time the treatment is begun.
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 of the treatment to be performed for my patient record only, and I understand that it will not be shared with anyone without my consent.
6. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE TREATMENT TO BE UNDERTAKEN
    b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
    c. THERE ARE RISKS TO THE TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-6). I AM SATISFIED WITH THE EXPLANATION.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____